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PROVISIONAL APPLICATION COVER SHEET

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TITLE OF INVENTION (280 characters max)

INFUSION SET

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Respectfully submitted,

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PROVISIONAL APPLICATION FILING ONLY

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PROVISIONAL APPLICATION FOR UNITED STATES LETTERS PATENT

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Infusion set

The technical field

The invention relates to an infusion set for an intermittent or continuous administration of a therapeutical substance, such as insulin. An infusion set comprises an infusion part with a cannula to penetrate the skin of a person and a connector for connecting the infusion part with a medical device preferably a medical delivery device such as an insulin pump.

An infusion set has in its assembled form a substantially planar rear side and a relatively large width compared to its thickness; thus allowing it to lie flat on the patient's skin and thereby minimizing the discomfort of carrying the infusion set.

The infusion part is placed in the patient for a longer and not specified time period while the connector is supposed to be connected and disconnected from time to time. Hereby it is possible for the patient to disconnect from the medical device, move around and at a later point re-connect to the medical device. Further it is possible to shift between different medical devices using the same infusion part and thereby there is only need for one penetration of the skin which provides less discomfort to the patient.

Prior art

US 5 522 803 discloses an infusion set having an infusion part and a connector. The infusion part comprises a soft plastic cannula in liquid communication with a cavity for receiving a needle from a connector, two sloping guiding holes and two retention devices; and the connector comprises a cannula, two square guiding pins and two arms with a hooking

part for gripping the retention device of the infusion part and operating in the main plane of the infusion part.

Given that the infusion part is supposed to be connected and especially disconnected several times with the connector it is important that this operation is as painless as possible. The object of the invention is therefore to provide an infusion set with a coupling mechanism that can be separated with less discomfort to the patient than the previously known infusion sets.

According to the invention there is provided an infusion set comprising an infusion part for insertion into a patient and a connector for connecting the infusion part with a medical device through a tube, the connector being axially displaceable relative to the infusion part, said infusion part comprising an adhesive support, a base part with a first set of guiding means and at least two retention devices for locking the infusion part to the connector, a cannula extending from said base part and being in fluid communication with a cavity which is optionally covered with a membrane, said cavity being further adapted for receiving a cannula extending from the connector, said connector comprising a cannula in fluid communication with said tube, a second set of guiding means adapted to fit with the first set of guiding means and at least two arms characterized in that the retention devices are extending from the upper surface of the main surface of the base part.

The above described infusion set is easier to disconnect than the previously known infusion sets. All that is needed to separate the connector from the infusion part is a slight pressure on the top part of the connector or an easy lifting of the arms of the connector.

With the term cavity is meant the inner lumen of the cannula or the extension of said cannula.

In a preferred embodiment the connector is symmetrical both around the main plain of the connector and around the plane being perpendicular to the main plane and being parallel to the central axis, thus allowing the connector to be connected to the infusion part no matter which of the main sides is facing upwards. This results in a much easier operation of the infusion set.

In another preferred embodiment the arms of the connector have gripping means for getting a better grip of the connector. Examples of such gripping means could be but are not limited to rims, grooves, recesses, a roughened surface optionally of another material than the connector itself, preferably recesses are used. This results in a safer and more comforting operation of the infusion set since the risk that the fingers slip during handling resulting in unintended movements of the infusion part and the cannula is reduced.

In a preferred embodiment the retention devices are in form of at least two steps placed on either the infusion part or the connector and a matching carving in the other part. Preferably the step has a side with a triangular shape thus forming the step as a sloping hill. Preferably the retention devices are placed on the infusion part and the matching carvings are placed in the connector's arms.

In one embodiment of the invention the connector has at least one groove, preferably at least two grooves, placed in the guiding means of the connector, thus allowing the arms of the connector to rock relative to the guiding means. Hereby it is achieved that connection/disconnection can be performed in a manner which at the same time reduces the stresses in the material during the operation, eases the operation of the locking mechanism and reduces the patient's unpleasantness during the connection/release of the connector.

In another embodiment the main part of the infusion part has at least two cuttings creating at least two flaps. The created flaps are able to in an elastic manner to move out of the main plane of the infusion part. Hereby the same advantages during connection/release as described above are obtained.

In a preferred embodiment the tube is a flexible plastics material which preferably is connected with the rest of the connector by means of glue.

In a preferred embodiment the cannula of the connector is a hard cannula, preferably a metal cannula such as a steel cannula.

In another preferred embodiment the cannula of the connector is made of a plastics material and/or being blunt.

In a preferred embodiment the cannula of the infusion part penetrates the adhesive support, thus stabilizing the position of the infusion part relative to the point of skin penetration to an even greater extend. Further this minimizes the risk that the cannula accidentally is withdrawn from the patient.

In a preferred embodiment the cannula is a soft cannula preferably a soft cannula made of a plastics material. Preferred plastics materials for the soft cannula are materials which are sufficiently flexible to bend, when the patient moves and sufficiently rigid to avoid kinking closing off the drug supply. Further the material must be compatible with medical use i.e. irritation of the skin must be kept at a minimum, being non-toxic it must not decompose in the body, etc. Thermoplastic elastomers (TPE) are a type of material which fulfils these requirements. Examples of such useful elastomers are: polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefines and silicone rubbers. In a preferred embodiment the material is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene,

LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™.

In a preferred embodiment the adhesive support is a plaster.

In a preferred embodiment there is an opening in the adhesive support. This provides the possibility of securing the adhesive support in a position which minimizes the risk for an undesired folding during insertion.

In a preferred embodiment the infusion part and the connector are made of polypropylene.

In a preferred embodiment the infusion part and the connector are made from two different plastics materials, such as two different types of polypropylene.

In a preferred embodiment there is a visual difference in the toning of the connector and the base part of the infusion part. Hereby it is achieved that it is easier for the patient to see the separation line between the two units resulting in an easier operation of the locking mechanism.

Preferably the medical delivery device is a drug delivery device such as an insulin delivery device.

Given that the infusion part is supposed to be connected and especially disconnected several times with the connector it is important that the cannula of the connector is guided safely into the cavity of the infusion part and that the cannula in the disconnected situation is protected as much as possible. It is therefore a further object of the invention to provide an infusion set with an improved guiding mechanism and with an improved protection of the connector cannula.

In a second aspect of the invention there is provided an infusion set comprising an infusion part for insertion into a patient and a connector for connecting the infusion part with a medical device through a tube, the connector being axially displaceable relative to the infusion part, said infusion part comprising an adhesive support, a base part with a first set of guiding means and at least two retention devices for locking/releasing the insertion part to/from the connector, a cannula extending from said base part and being in fluid communication with a cavity which is optionally covered with a membrane, said cavity being further adapted for to receive a cannula extending from the connector, said connector comprising a cannula in fluid communication with said tube, a central part with a second set of guiding means adapted to fit with the first set of guiding means and at least two arms characterized in that the connector cannula is extending from the central part of the connector and being placed in a withdrawn position relative to the front of the central part and that at least one of the first set of guiding means comprises at least two stabilizing fins.

The above described invention provides an infusion set with an improved protection of the cannula of the connector thus allowing the connector to be connected and disconnected from the infusion part more times than in the previously known infusion sets.

With the term cavity is meant the inner lumen of the cannula or the extension of said cannula.

In a preferred embodiment the connector is symmetrical both around the main plane of the connector and the plane being perpendicular to the main plane and being parallel to the central axis, thus allowing the connector to be connected to the infusion part no matter which of the main sides is facing upwards. This results in a much easier operation of the infusion set.

In another preferred embodiment the arms of the connector have means for getting a better grip of the connector. Examples of such means could be but are not limited to rims, grooves, recesses, a roughened surface optionally of another material than the connector itself, preferably recesses are used. This results in a safer and more comforting operation of the infusion set since the risk that the fingers slip during handling resulting in unintended movements of the infusion part and the cannula is reduced.

In a preferred embodiment the retention devices are in form of at least two steps placed on either the infusion part or the connector and a matching carving in the other part. Preferably the step has a side with a triangular shape thus forming the step as a sloping hill. Preferably the retention devices are placed on the upper surface of the infusion part and the matching carvings are in the connector.

In one embodiment of the invention the connector has at least one groove, preferably at least two grooves, placed in the guiding organs of the connector, thus allowing the arms of the connector to rock relative to the guiding organs. Hereby it is achieved that connection/disconnection can be performed in a manner which at the same time reduces the stresses in the material during the operation, ease the operation of the locking mechanism and reduces the patient's unpleasantness during the connection/release of the connector.

In another embodiment the main part of the infusion part has at least two cuttings creating at least two flaps. The created flaps are able to in an elastic manner to move out of the main plane of the infusion part. Hereby the same advantages during connection/release as described above are obtained.

In a preferred embodiment the tube is a flexible plastics material which preferably is connected to the rest of the connector by means of glue.

In a preferred embodiment the cannula of the connector is a hard cannula, preferably a metal cannula such as a steel cannula.

In another preferred embodiment the cannula of the connector is made of a plastics material and/or being blunt.

In a preferred embodiment the cannula of the infusion part penetrates the adhesive support, thus stabilizing the position of the infusion part relative to the point of skin penetration to an even greater extent. Further this minimizes the risk that the cannula accidentally is withdrawn from the patient.

In a preferred embodiment the cannula is a soft cannula preferably a soft cannula made of a plastics material. Preferred plastics materials for the soft cannula are materials which are sufficiently flexible to bend, when the patient moves and sufficiently rigid to avoid kinking closing off the drug supply. Further the material must be compatible with medical use i.e. irritation of the skin must be kept at a minimum, being non-toxic it must not decompose in the body, etc. Thermoplastic elastomers (TPE) are a type of material which fulfils these requirements. Examples of such useful elastomers are: polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefines and silicone rubbers. In a preferred embodiment the material is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™.

In a preferred embodiment the adhesive support is a plaster.

In a preferred embodiment there is an opening in the adhesive support. This provides the possibility of securing the adhesive support in a position which minimizes the risk of an undesired folding during insertion.

In a preferred embodiment the infusion part and the connector are made of polypropylene.

In a preferred embodiment the infusion part and the connector are made from two different plastics materials, such as two different types of polypropylene.

In a preferred embodiment there is a visual difference in the toning of the connector and the base part of the infusion part. Hereby it is achieved that it is easier for the patient to see the separation line between the two units resulting in an easier operation of the locking mechanism.

Preferably the medical delivery device is a drug delivery device such as an insulin delivery device.

A lot of patients e.g. insulin patients have to or may desire to insert an infusion device or to place a subcutaneous sensor or the like themselves. For some persons it is a troublesome process to perform the skin penetration themselves and they therefore need a device which assists them in this process and thereby making the process less problematic.

US 2003/0225373 discloses an insertion device for inserting an infusion part or a sensor into a patient. The device comprises a housing, a coil spring, a safety device and part for angling the insertion into the patient. However the apparatus is relatively complicated to manufacture industrially and further the device has to be loaded manually by the patient by a rather complicated procedure.

WO 03/026728 A1 discloses an injector device comprising a housing, a spring, a slidable bar, a locking mechanism and a needle.

It is a further object of the invention to provide an improved insertion device which is easy to manufacture and which is suitable for being delivered in a loaded form or at least being easier to load. Especially elderly people who can have some motor problems need an insertion device which exists in a pre-loaded form.

According to the invention there is further provided an injector device for the subcutaneous introduction of the cannula of the infusion part of an infusion set into the skin of a patient said device comprising a housing, a back and longitudinally extending guiding means, a member which is longitudinally slidable within the housing and comprising a needle for insertion in the cavity of said cannula, a spring located between the back of the housing and the longitudinally slidable member, locking means for maintaining the spring in a compressed state and release means for disengaging the locking means characterized in that the device further comprises a pivoting member which can be swung from a position in which it is placed parallel to the housing into a position in which it embraces the needle.

The advantage in essentially vertical insertion is that it is easier to control the dept of the needle penetration and thereby the dept of the cannula. This is important in self-insertion of the infusion part.

In a preferred embodiment the insertion device has means for temporarily fixing the pivoting member in an essentially right angle relative to the housing thus stabilizing the insertion device in an essentially vertical position relative to the skin to be penetrated prior to penetration. This is particularly relevant for patients with motor problems since they can have problems to control the insertion angle.

In a preferred embodiment the housing has means for getting a better grip of the injector device. Examples of such means could be but are not limited to rims, grooves, recesses, a roughened surface optionally of another material than the housing itself, preferably recesses are used

In one embodiment the pivoting arms are also the locking means and it has a tab which functions as the disengaging means.

In a preferred embodiment of the invention the pivoting member of the injector device further has fixing means for temporarily fixing the adhesive support of the infusion part. Hereby it is achieved that the adhesive support does not fold in a unsuitable manner during insertion of the infusion part.

In another embodiment there is separate locking means and disengaging means. Preferably the pivoting member then still have a tab for securing the arm in a position parallel to the axis of the housing until it is desired to swing the pivoting member to the position in which it embraces the needle.

In a preferred embodiment the pivoting member embraces the needle in a first position being parallel to the main axis of the injector device then it is swung into second position being essentially orthogonal to said main axis and then finally swung into a position in which it embraces the needle.

In a preferred embodiment the pivoting member is swung from the position essentially orthogonal to said main axis, 180 degrees to another position embracing the needle and being secured in this position said position also being essentially orthogonal to said main axis. Optionally the needle is destroyed in the process and secured in the pivoting member.

In a preferred embodiment the injector device comprises means for stopping the slidable member in its most forward position preferably in form of a stopping tab.

In a preferred embodiment the injector device has a locking tab for fixing the pivoting member in a position embracing the needle.

In the following the invention will be described in further details with reference to the figures.

Figure 1 shows the infusion set in the connected position.

Figure 2 shows one embodiment of the infusion part and the connector from a first angle.

Figure 3 shows the same embodiment of the infusion part and the connector as in figure 2 but from a different angle.

Figure 4 shows a second embodiment of the infusion part and the connector from a first angle.

Figure 5 shows the same embodiment of the infusion part and the connector as in figure 4 but from a different angle.

Figure 6 shows a first embodiment of the injector device without an infusion part.

Figure 7 shows the first embodiment of the injector device joined with an infusion part.

Figure 8 shows the first embodiment of the injector device in a separated state joined with an infusion part.

Figure 9 shows the first embodiment of the injector device where the pivoting member is embracing the needle.

Figure 10 shows the first embodiment of the injector device in the loaded position.

Figure 11 shows the first embodiment of the injector device in the loaded position from a second angle.

Figure 12 shows a second embodiment of the injector device in a loaded and secured state.

Figure 13 shows the second embodiment of the injector device in a ready to use state.

Figure 14 shows the second embodiment of the injector device after the needle has penetrated the skin of a patient.

Figure 15 shows the second embodiment of the injector device after the needle has been withdrawn.

Figure 16 shows the second embodiment of the injector device after the pivoting arm has been swung into a position in which it embraces the needle.

Figure 17 shows the second embodiment of the injector device after the pivoting member has been swung into a position in which it embraces the needle seen from another angle.

Figure 18 shows an infusion set placed on the skin.

Figure 19 shows the second embodiment of the injector device together with a credit card.

Figure 20 shows a third embodiment of the injector device.

Figure 21 A-D shows how the connector device according to the third embodiment is composed.

Figure 22 A-B shows how the third embodiment of the injector device is prepared for insertion.

Figure 23 A-B shows how the adhesive support of the infusion part is hooked on to the slidable member.

Figure 24 A-B shows the injector prior to insertion with an infusion part and after insertion without the infusion part.

Figure 25 shows the third embodiment of the injector device after insertion.
Figures 26 A-D show the cyclus of use.

Figure 27 shows the third embodiment of the injector device where the pivoting member is in a first position embracing the needle.

Figure 28 A-D shows the housing of a fourth embodiment of the injector device.

Figure 29 A-C shows the slidable member of the fourth embodiment of the injector device.

Figure 30 A-B shows the slidable member joined with the infusion part.

Figure 31 A-D shows the fourth embodiment of the injector device in a secured state.

Figure 32 A-C shows the injector device according to the fourth embodiment of the invention.

Figure 33 A-B shows the injector device according to the fourth embodiment where the slidable member is in its most forward position.

Figure 34 A-B shows the injector device according to the fourth embodiment in which the pivoting member is in a position in which it embraces the needle.

Figure 35 A-D shows the cyclus of use for the fourth embodiment of the injector device.

Figure 1 illustrates one embodiment of an assembled infusion set. The infusion set comprises an infusion part (0B) and a connector (0A). Referring to figures 2 and 3 one embodiment of the invention will be described in further details. The infusion part comprises a base part (2) having a main plane which, when the infusion set is attached to a patient, is essentially parallel with the skin of the patient. Said base part comprises a first set of guiding means (13) which in this case is in form of two stabilizing fins. The base part further comprises two retention devices (4) extending from the upper surface of the base part in this case in form of two steps. Mounted on the inner surface of the infusion part is an adhesive support (1) which in this case is a plaster. A cannula (5) is extending from the base part (2), said cannula is penetrating the adhesive support (1) and being in fluid communication with a cavity (3). The cannula (5) is preferably a soft cannula. The cavity (3) optionally being covered by a membrane is adapted to receive

a cannula (6) extending from the connector. In this particular embodiment the cannula (6) is extending from the central part of the connector and is positioned in a retracted position relative to the front of the central part. In this embodiment the base part (2) has two cuttings (12) creating two flaps on which the retention devices (4) are mounted. The connector comprises two arms (9) having four carvings (10) adapted to fit with the retention devices (4). The connector is symmetrical around the main plane and around the plane perpendicular to the main plane and parallel to the main axis thus allowing the connector to match with the base part in two ways. The cannula (6) is in fluid communication with the tube (7) which provides the connection to a medical device such as an insulin pump. In this embodiment the central part of the connector has a second set of guiding means (8) in form of two grooves placed symmetrically around the main plane of the connector. In this embodiment the connector further has gripping means (11) in form of recesses.

Figures 4 and 5 show another embodiment of the invention in which the connector has two grooves (14) which in this case are placed symmetrically around the main plane of the connector. However it is not necessary for the grooves to be places symmetrically around the main plane since they are not coupling with the infusion part

Figure 6 shows a first embodiment of the injector device (29) in which the injector device is not joined with the infusion part (0B) and figure 7 shows the same injector device (29) joined with an infusion part (0B). In figure 8 the pieces of the injector device are separated for a better view. The injector device comprises a housing (30) with two longitudinally extending guiding means (31) and a longitudinally slidable member (32) which in this case further has a rim (38). The slidable member is capable of moving from a retracted position to a forward position, and is driven from the retracted position to the forward position by a spring (34). The spring is located

between the slidable member (32) and the back (33) of the housing. Optionally there is a spring support (37) which fits with the back of the housing thereby minimizing the risk of a malfunctioning spring. The injector device further comprises locking means (not shown) for maintaining the spring in a compressed state and release means (not shown) for disengaging the locking means. When the locking means is disengaged, the spring (34) drives the slidable member (32) to its forward position, thus introducing the cannula of the infusion part into the patient by means of the needle (35). After the introduction of the cannula the injector device can be withdrawn leaving the needle in a free position. The pivoting member (36) is then swung into a position in which it embraces the needle (35) as shown in figure 9.

Figure 10 and figure 11 show the injector device in a loaded position, and in this particular embodiment the pivoting member (36) further acts as the locking mean. In Figure 10 it can be seen how the needle (35) fits into the cannula (5) of the infusion part. The needle will bring the cannula (5) with it during the skin penetration. After the skin penetration the needle (35) can be withdrawn leaving the cannula inserted in the patient. In figure 11 the locking means are shown said locking means are disengaged when the tab (38) is pushed over the edge of the outer side of the back (33) of the housing.

Figures 12 to 17 show a second embodiment of the injector device according to the invention. Figure 12 shows the injector device in a state where the pivoting member (36) protects the needle prior to injection of the infusion part (0B). The figure shows the housing (30) with another type of longitudinally extending guiding means (31), in this case a bar. The housing further has recesses (40) as means for getting a better grip of the injector device. A centrally positioned release means (39) is shown on one of the main faces of the injector device. The advantage of a one button release mechanism is that the risk of a slanting injection. In figure 13 it is shown how the injector device is prepared for insertion of the needle. The pivoting member is swung away

from the embracing position and the adhesive support (1) is bend in such manner that the cannula of the infusion part and the therein positioned injector needle penetrates the main plane of the adhesive support. In a preferred embodiment the pivoting member is positioned essentially perpendicular to the main plane of the injector device so as to provide a helping mean for achieving essentially vertical injection of the needle. Further figure 13 shows how the needle (35) of the injector device is inside the cannula (5). Figure 14 shows the injector device in a state where the needle just has penetrated the skin. Further figure 14 shows a stopping tab (43) which keeps the slidable member within the housing and thereby makes it easier to withdraw the needle since there is no risk that the slidable member slides out of the housing. Figure 15 shows the withdrawal of the injector device leaving the infusion set (0B). It can be seen that the needle (35) has been withdrawn from the cannula (5). Figures 16 and 17 show how the pivoting member (36) is swung into a position where it embraces the needle (35). Figure 18 shows how the infusion part is swung from the essentially vertical position to the position essentially parallel to the skin.

Figure 19 shows the injector device together with a credit card to illustrate the size of the injector device.

Figure 20 shows a third embodiment of the connector device together with an infusion part (0B). Once again the housing (30) with longitudinally extending guiding means (31) and the longitudinally slidable member (32) are illustrated. Further the pivoting arm (36) and the spring (34) can be seen. Figure 21 A-D shows how the infusion part (0B) along with the slidable member (32) and the spring (34) fit into the housing (30). Figure 22 A-B shows the fixing means (44) of the pivoting member (36) on which the adhesive support (1) temporarily is hooked on. Further two release means (39) can be seen as well as the stopping tab (43).

Figure 23 A-B shows in further details how the adhesive support (1) is hooking on to the fixing means (44) due to at least one cutting in the adhesive support (1).

Figure 24 A-B illustrates the injector device with an infusion part prior to insertion and 24 B the injector device just after insertion.

Figure 25 shows the third embodiment of the injector device where the pivoting member (36) has been swung into a position embracing the needle and where a locking tab (45) fixes the pivoting arm in this position. This makes certain that the needle stays embraced by the pivoting arm and thereby minimizes the risk of somebody getting hurt by the needle.

Figure 26 A-D illustrates the cyclus of use for the injector device. The device in a first state (26A), then the device is prepared for use (26B) after which the release means are pressed and the needle is inserted (26C) and finally after withdrawal of the needle the pivoting member is swung into the position embracing the needle.

Figure 28 A-D shows the housing (30) of the injector device according to a fourth embodiment of the injector device. In the housing the longitudinally extending guiding means (31) and the stopping tab (43) is seen. On the side of the housing (30) the release means (39) can be seen. Figure 29 A-C shows the slidable member (32) and the spring (34) which is supposed to drive it from the rear position to the forward position. On the slidable member guiding tips (47) are positioned, said guiding tips (47) fitting with the longitudinally guiding means. In figure 29 C the three main positions of the pivoting member are shown. Figure 30 A-B shows the slidable member joined with an infusion part. Figure 31 A-D shows the injector device in a state, where the needle is protected by the pivoting arm. Figure 32 A-C shows the pivoting member being swung from the position where it protects

the needle and into a ready-to-use position. In figure 32 B the adhesive support (1) is temporarily fixed to the pivoting arm thus preventing the adhesive support from folding during insertion of the needle into the patient. Figure 33 A-B shows the injector device with the slidable member in its most forward position. Figure 34 A-B shows the injector device where the pivoting arm has been swung into a position in which it embraces the needle.

Figure 35 A-D illustrates the cyclus of use of the injector device. The device in a first state (35A) the device, then the device is prepared for use (35B) after which the release means are pressed and the needle is inserted (35C) and finally after withdrawal of the needle the pivoting member is swung into the position embracing the needle.

CLAIMS

1. An infusion set comprising an infusion part (0B) for insertion into a patient and a connector (0A) for connecting the infusion part (0B) with a medical device through a tube (7), the connector being axially displaceable relative to the infusion part, said infusion part comprising an adhesive support (1), a base part (2) with a first set of guiding means (13) and at least two retention devices (4) for locking the insertion part to the connector, a cannula (5) extending from said base part (2) and being in fluid communication with a cavity (3) which is optionally covered with a membrane, said cavity being further adapted to receive a cannula (6) extending from the connector, said connector comprising a cannula (6) in fluid communication with said tube (7), a second set of guiding means (8) adapted to fit with the first set of guiding means (13) and at least two arms (9) characterized in that the retention devices (4) are extending from the upper surface of the main surface of the base part (2).

2. An infusion set according to claim 1, characterized in that the second set of guiding means has at least one groove.

3. An infusion set according to claim 1 or 2, characterized in that the connector is symmetrical around the main plane of the connector and around the plane perpendicular to the main plane and parallel to the central axis.

4. An infusion set according to any one of the preceding claims, characterized in, that the arms (9) have gripping means.

5. An infusion set according to claim 4, characterized in that the gripping means are selected from the group consisting of rims, grooves, recesses, a roughened surface optionally of another material than the connector itself.

6. An infusion set according to any one of the preceding claims, characterized in that base part (2) has at least two cuttings creating at least two flaps.

7. An infusion set according to any one of the preceding claims, characterized in that the cannula penetrates the adhesive support.

8. An infusion set according to any one of the preceding claims, characterized in that the adhesive support is a plaster.

9. An infusion set according to any one of the preceding claims, characterized in that the infusion part and the connector are made from two different plastics materials.

10. An infusion set according to any one of the preceding claims, characterized in that there is a visual difference in the toning of the connector and the base part of the infusion part.

11. An infusion set according to any one of the preceding claims, characterized in that the retention devices (4) are in form of a step.

12. An infusion set according to any one of the preceding claims, characterized in that the retention devices (4) have a triangular shape.

13. An infusion set according to claim 12, characterized in that the arms have carvings matching the retention devices.

14. An infusion set according to any one of the preceding claims, characterized in that the tube is fastened by means of a glue.

15. An infusion set according to any one of the preceding claims, characterized in that the cannula is a metal cannula.

16. An infusion set according to any one of the preceding claims, characterized in that the cannula is a soft cannula.

17. An infusion set according to any one of the preceding claims, characterized in that the medical device is an insulin pump

18. An infusion set according any one of the preceding claims, characterized in that the soft cannala is made of thermoplastic elastomers (TPE).

19. An infusion set according to claim 18, characterized in that the thermoplastic elastomer is selected from the group consisting of polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefines and silicone rubbers.

20. An infusion set according to claim 19, characterized in that the thermosplastic elastomer is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™

21. An infusion set according to any one of the preceding claims, characterized in that the infusion part and/or the connector essentially is made of popypropylene.

22. An infusion set comprising an infusion part (0B) for insertion into a patient and a connector (0A) for connecting the infusion part (0B) with a medical device through a tube (7), the connector being axially displaceable relative to the infusion part, said infusion part comprising an adhesive support

(1), a base part (2) with a first set of guiding means (13) and at least two retention devices (4) for locking/releasing the insertion part to/from the connector, a cannula (5) extending from said base part (2) and being in fluid communication with a cavity (3) which is optionally covered with a membrane, said cavity being further adapted to receive a cannula (6) extending from the connector, said connector comprising a cannula (6) in fluid communication with said tube (7), a central part with a second set of guiding means (8) adapted to fit with the first set of guiding means (13) and at least two arms (9), characterized in that the connector cannula (6) is extending from the central part of the connector and being placed in a withdrawn position relative to the front of the central part and that at least one of the first set of guiding means (13) comprises at least two stabilizing fins.

23. An infusion set according to claim 22, characterized in that the second set of guiding means has at least one groove.

24. An infusion set according to claim 22 or 23, characterized in that the connector is symmetrical around the main plane of the connector and around the plane perpendicular to the main plane and parallel to the central axis.

25. An infusion set according to any one of claims 22 - 24, characterized in that the arms (9) have gripping means.

26. An infusion set according to claim 25, characterized in that the gripping means are selected from the group consisting of rims, grooves, recesses, a roughened surface optionally of another material than the connector itself.

27. An infusion set according to any one of claims 22 - 26, characterized in that base part (2) has at least two cuttings creating at least two flaps.

28. An infusion set according to any one of claims 22 - 27, characterized in that the cannula penetrates the adhesive support.

29. An infusion set according to any one of claims 22 - 28, characterized in that the adhesive support is a plaster.

30. An infusion set according to any one of claims 22 - 29, characterized in that the infusion part and the connector are made from two different plastics materials.

31. An infusion set according to any one of claims 22 - 30, characterized in that there is a visual difference in the toning of the connector and the base part of the infusion part.

32. An infusion set according to any one of claims 22 - 31, characterized in that the retention devices (4) are in form of a step.

33. An infusion set according to any one of claims 22 - 32, characterized in that the retention devices (4) have a triangular shape.

34. An infusion set according to claim 33, characterized in that the arms have carvings matching the retention devices.

35. An infusion set according to any one of claims 22 - 34, characterized in that the tube is fastened by means of a glue.

36. An infusion set according to any one of claims 22 - 35, characterized in that the cannula is a metal cannula.

37. An infusion set according to any one of claims 22 - 36, characterized in that the cannula is a soft cannula.

38. An infusion set according to any one of claims 22 - 37, characterized in that the medical device is an insulin pump

39. An infusion set according any one of claims 22 – 38, characterized in that the soft cannala is made of thermoplastic elastomers (TPE).

40. An infusion set according to claim 39, characterized in that the thermoplastic elastomer is selected from the group consisting of polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefines and silicone rubbers.

41. An infusion set according to claim 40, characterized in that the thermosplastic elastomer is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™

42. An infusion set according to any one of claims 22 – 41, characterized in that the infusion part and/or the connector essentially is made of popypropylene.

43. An injector device for the subcutaneous introduction of the cannula (5) of the infusion part (0B) of an infusion set into the skin of a patient said device comprising a housing (30), a back (33) and longitudinally extending guiding means (31), a member (32) which is longitudinally slidable within the housing (30) and comprising a needle (35) for insertion in the cavity of said cannula, a spring (34) located between the back of the housing and the longitudinally slidable member, locking means for maintaining the spring in a compressed state and release means (39) for disengaging the locking means, characterized in that the device further comprises a pivoting member (36)

which can be swung from a position in which it is placed parallel to the housing into a position in which it embraces the needle.

44. An injector device according to claim 43, characterized in that the device further comprises a locking tab (45).

45. An injector device according to claim 43 or 44, characterized in that the pivoting member has fixing means for temporarily fixing the adhesive support of an infusion part.

46. An injector device according to any one of claims 43 to 45, characterized in that injector device has means (44) for fixing the pivoting member in an essentially right angle relative to the housing.

47. An injector device according to any one of claims 43 to 46, characterized in that the housing has gripping means.

48. An injector device according to claims 47, characterized in that the gripping means are in form of recesses.

49. An injector device according to any one of claims 43 to 48, characterized in that the housing has stopping means (43), preferably a stopping tab.

C-FLEX® compounds are, for example, silicone modified styrenic thermoplastic elastomers. Each formulation contains styrene ethylene butylenes styrene (SEBS) block copolymer, polypropylene, mineral oil, and silicone oil. C-FLEX® compounds are available from Consolidated Polymer Technologies, Inc., Clearwater, FL.

LUPOLEN® compounds are, for example, elastomers available from BASF Aktiengesellschaft, Germany.

PELLETHANE® compounds are, for example, thermoplastic polyurethane elastomers available from the Dow Chemical Company, Midland, MI.

TECOTHANE® compounds are, for example, a family of aromatic, polyether-based polyurethanes available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane resins to exhibit improved solvent resistance and biostability when compared with Tecoflex resins of equal durometers. As with any aromatic polyurethane, Tecothane resins tend to yellow upon aging or when subjected to radiation sterilization. Tecothane® compounds are available from Noveon Inc. Cleveland, OH.

CARBOTHANE® compounds are, for example, a family of aliphatic, polycarbonate-based polyurethanes available over a wide range of durometers, colors, and radiopacifiers. This type of TPU has been reported to exhibit excellent oxidative stability, a property which may equate to excellent long-term biostability. This family is easy to process and does not yellow upon aging. Carbothane® compounds are available from Noveon Inc., Cleveland, OH.

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FIG. 1

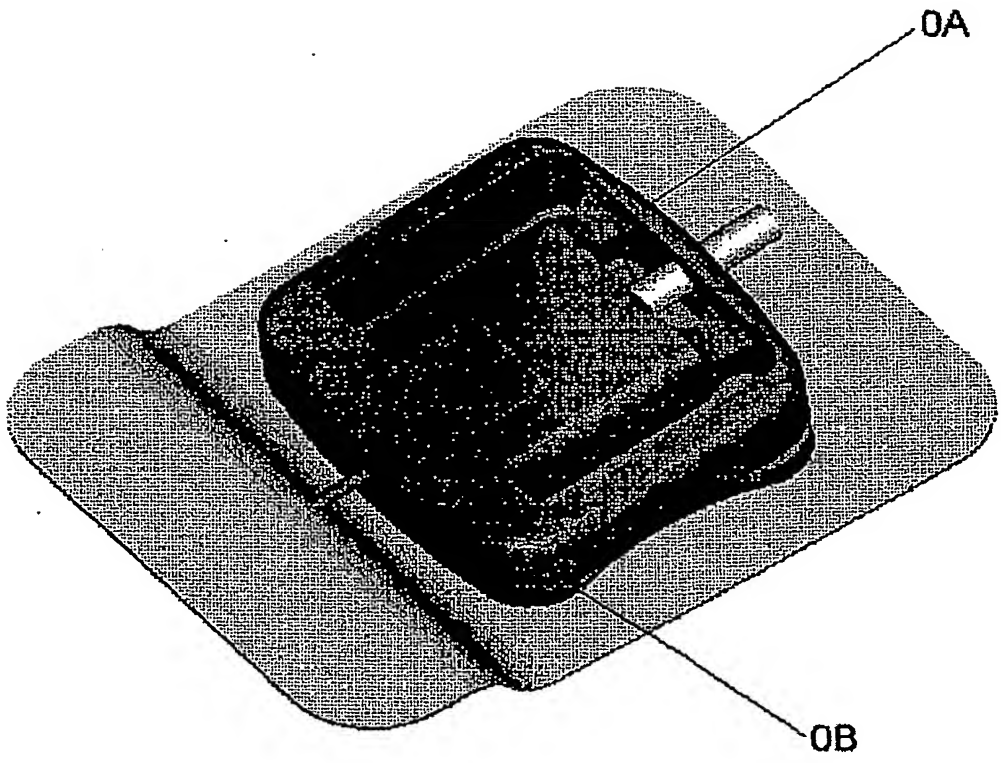


FIG. 2

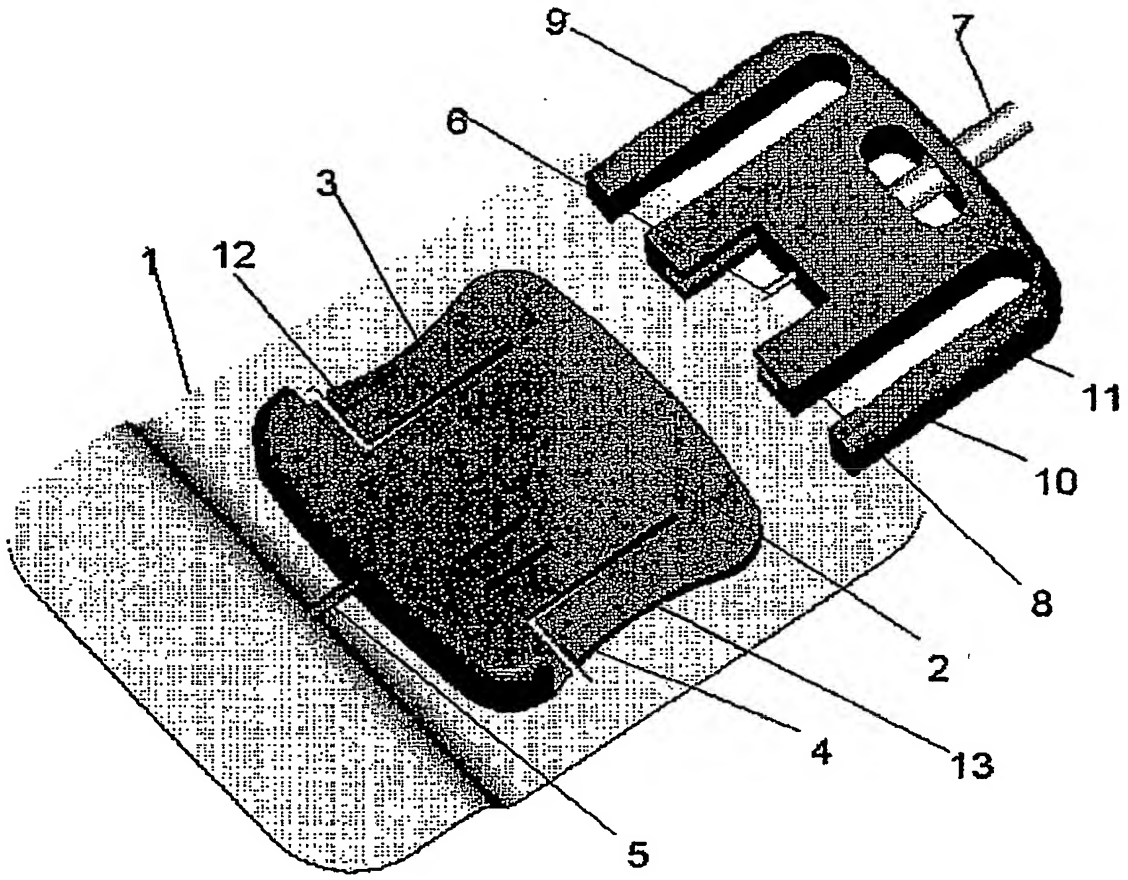


FIG. 3

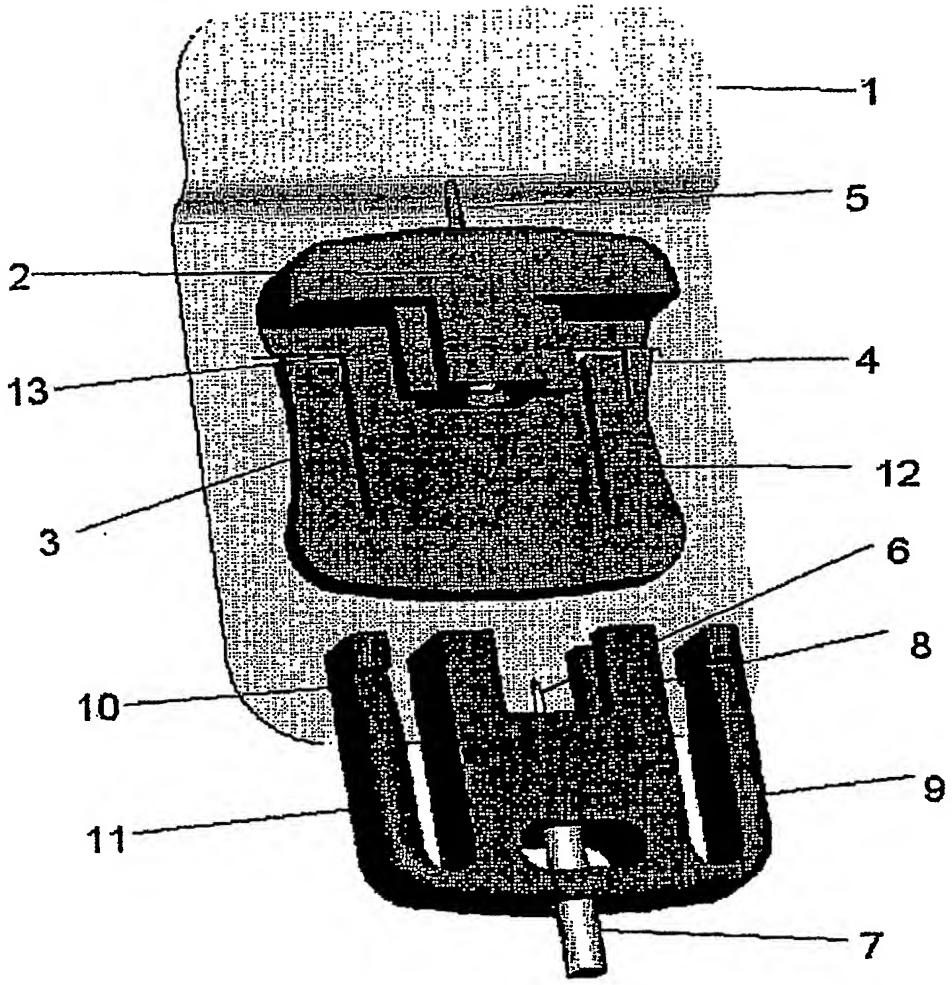


FIG. 4

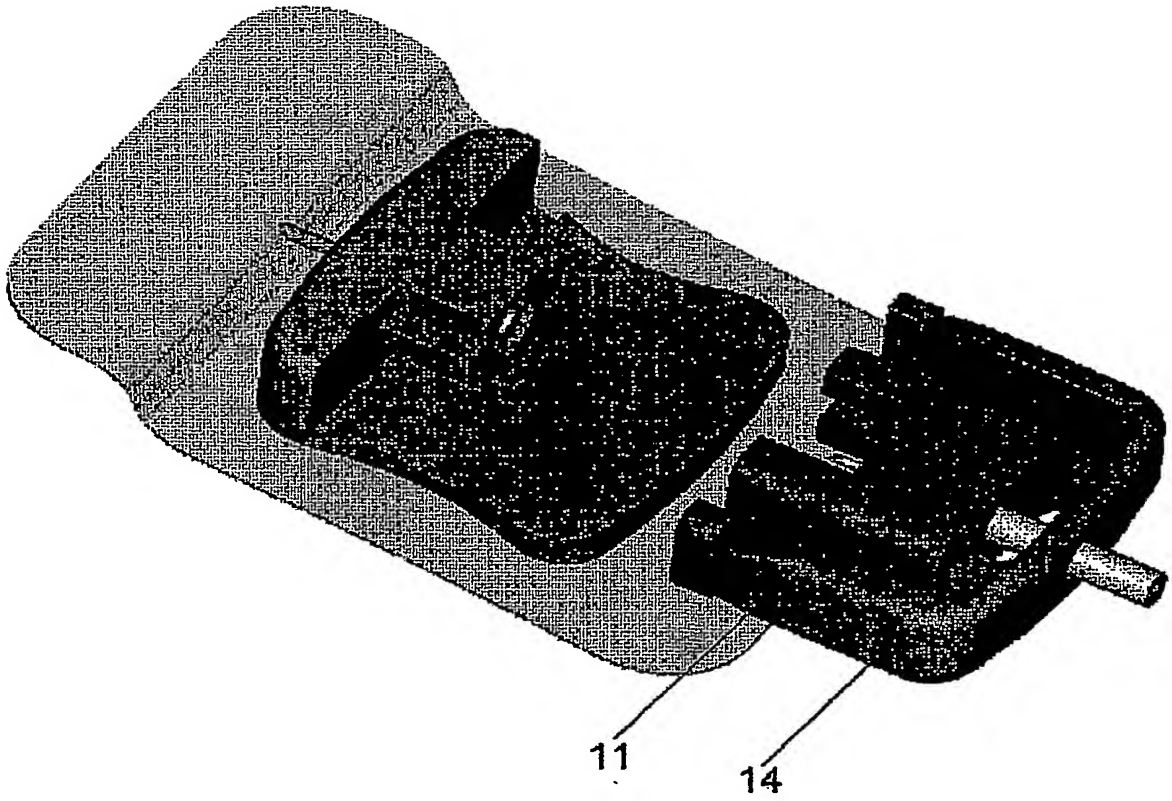


FIG. 5

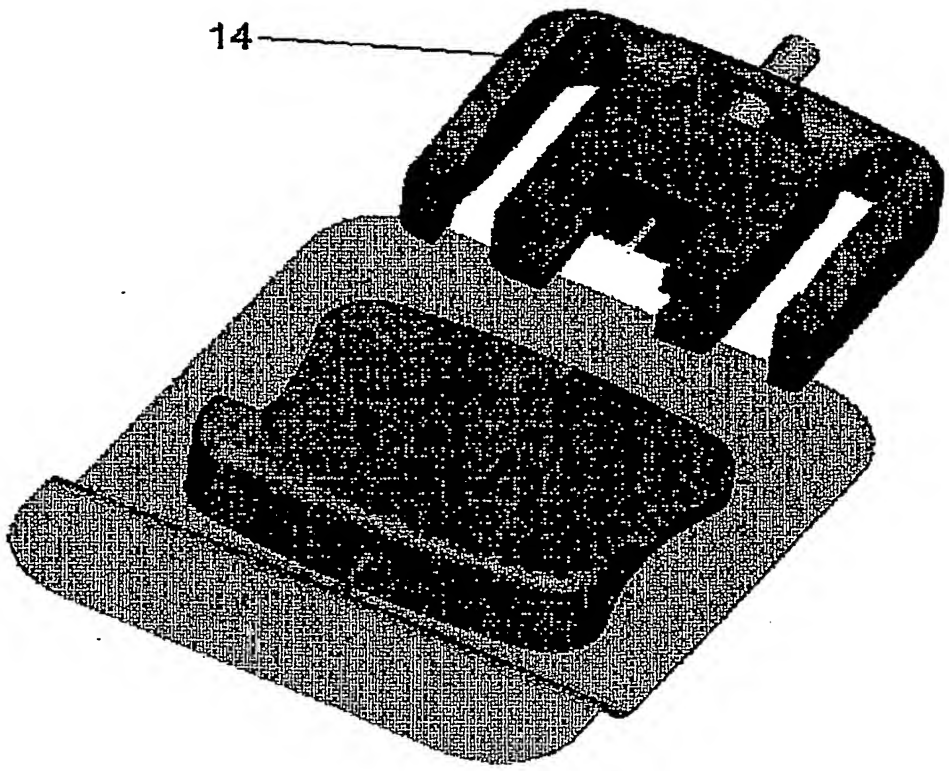


FIG. 6

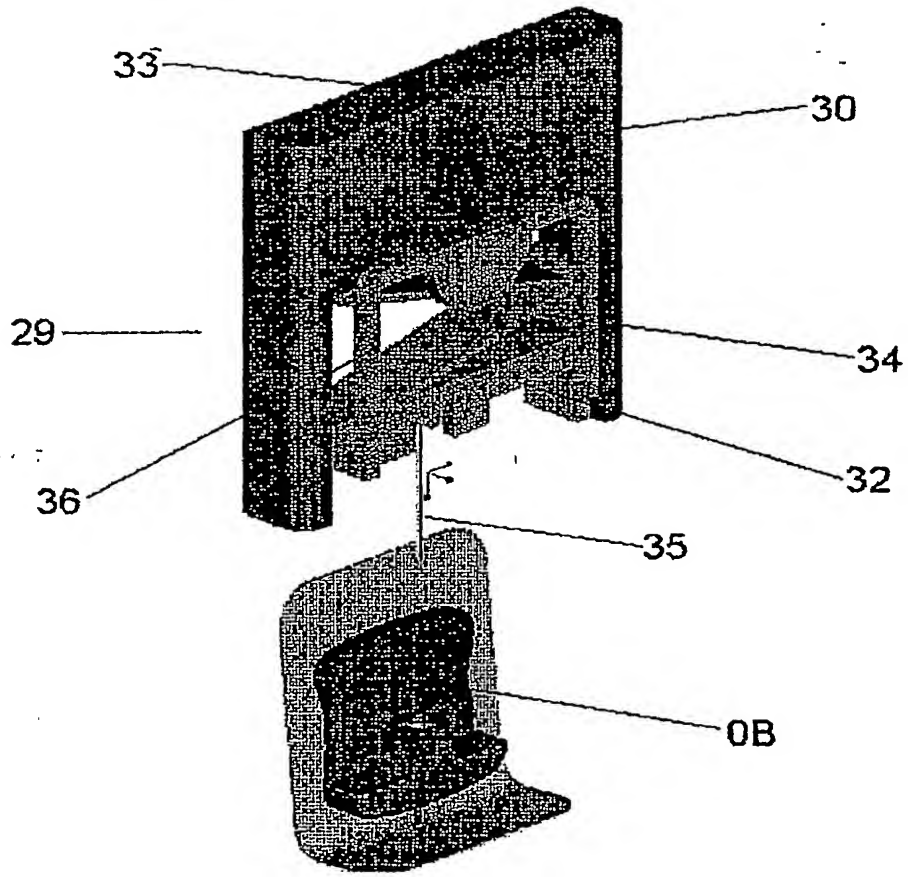


FIG. 7

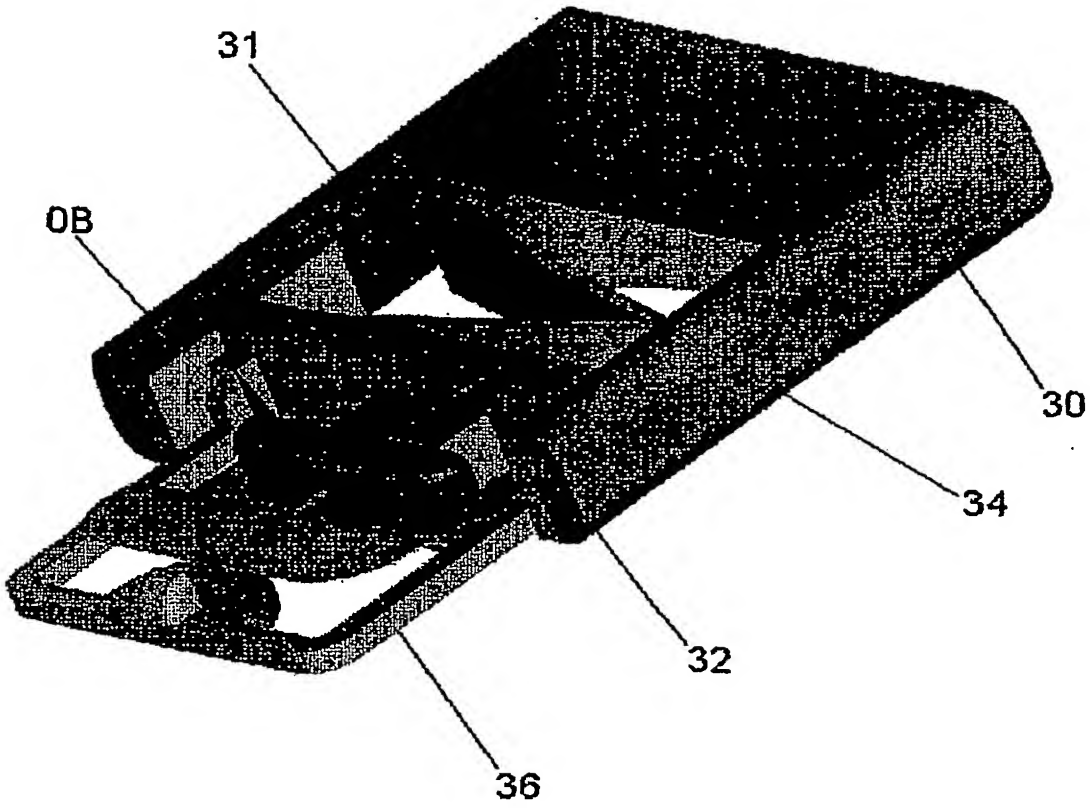


FIG. 8

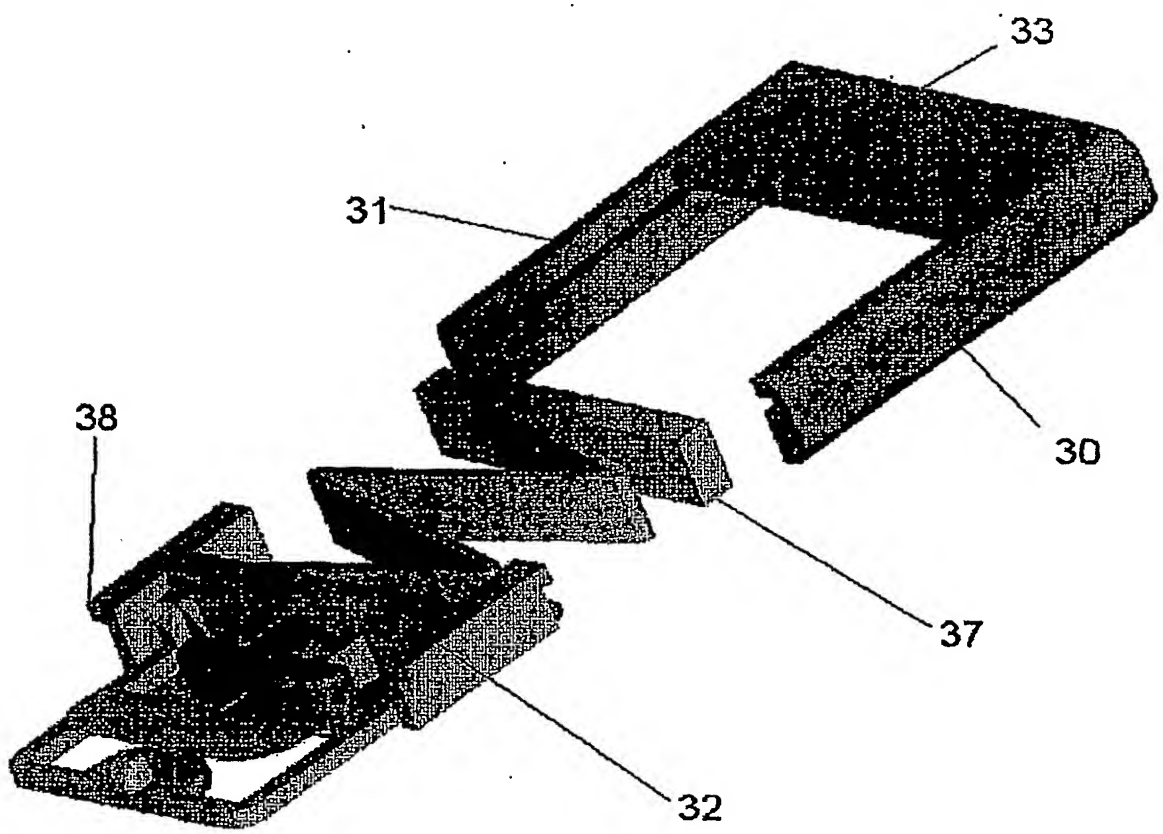


FIG. 9

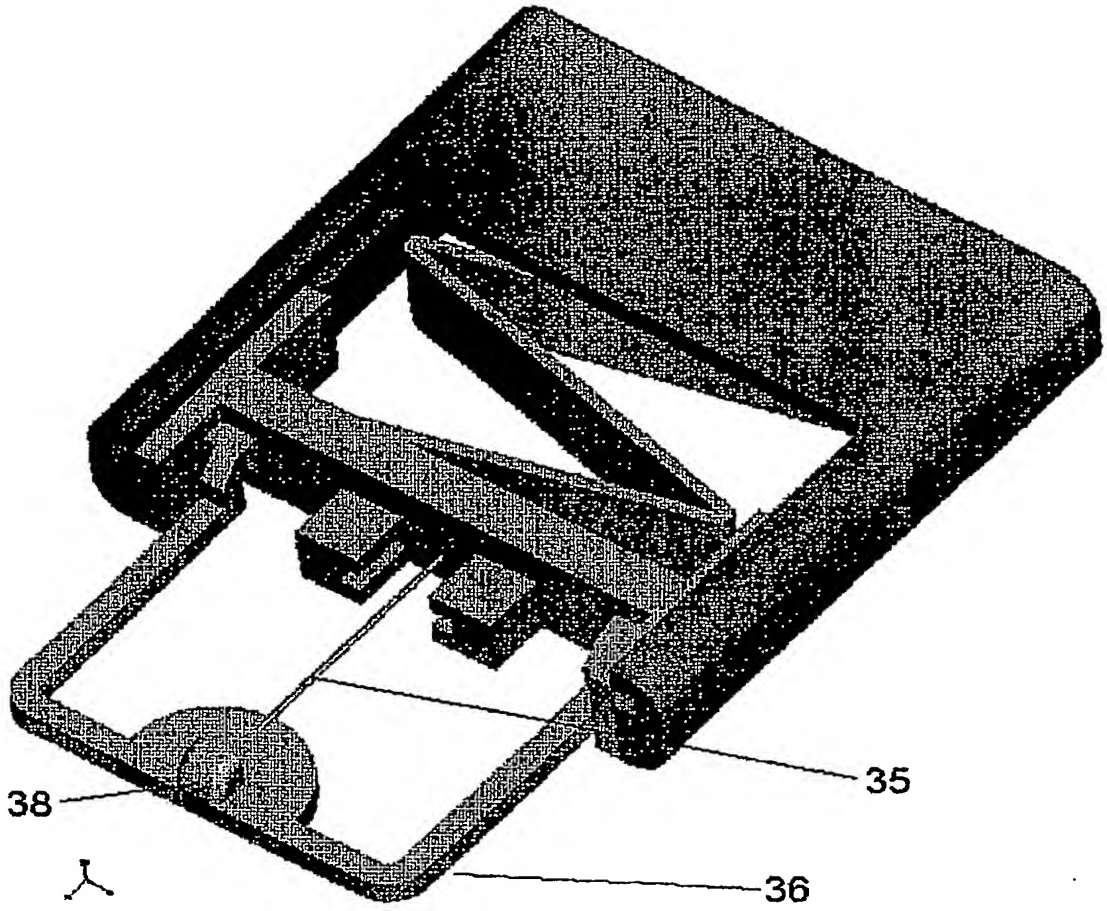


FIG. 10

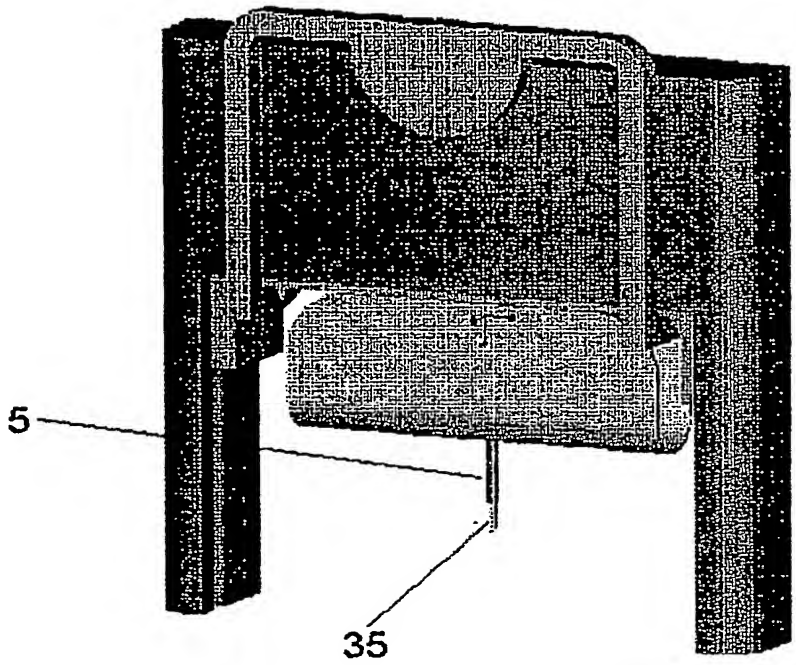


FIG. 11

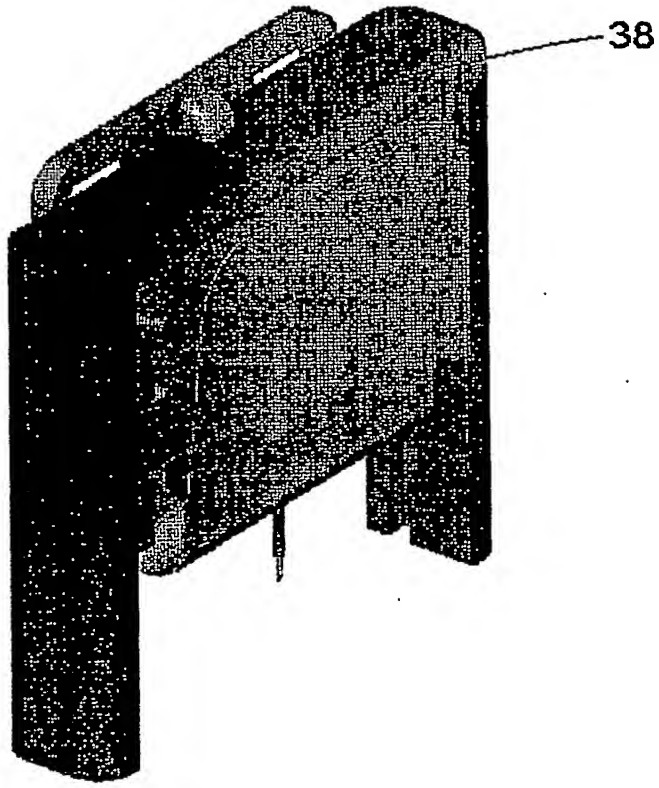


FIG. 12

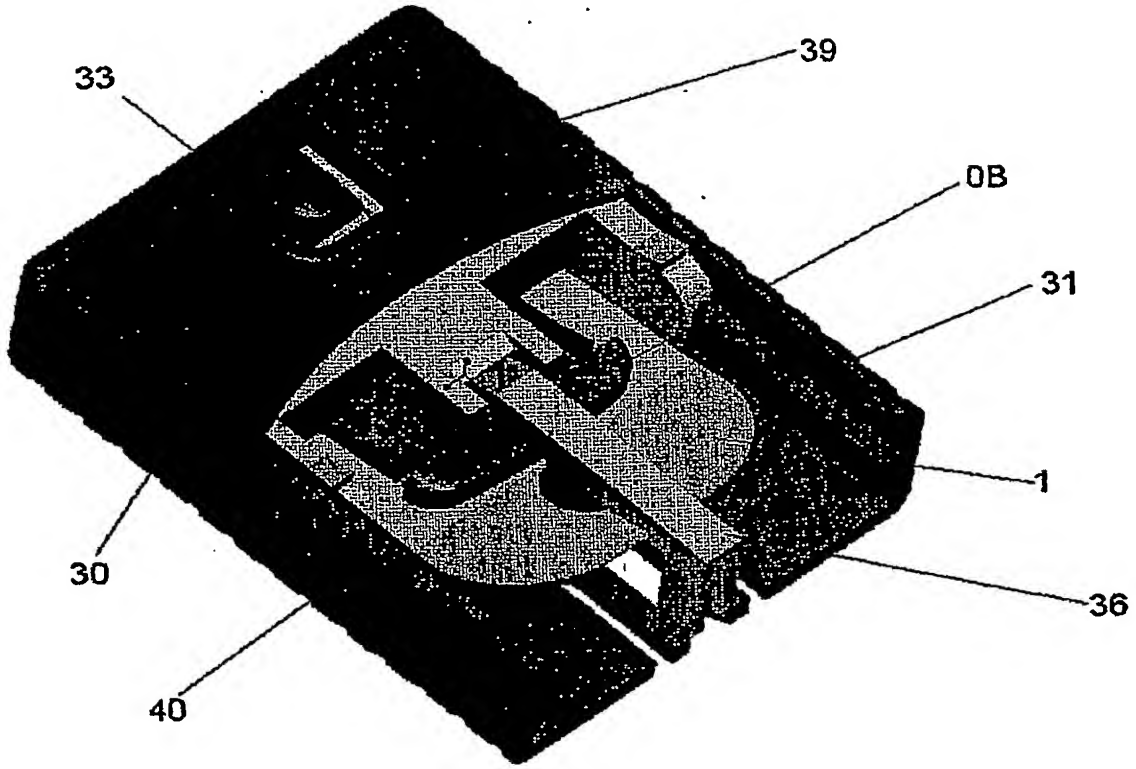


FIG. 13

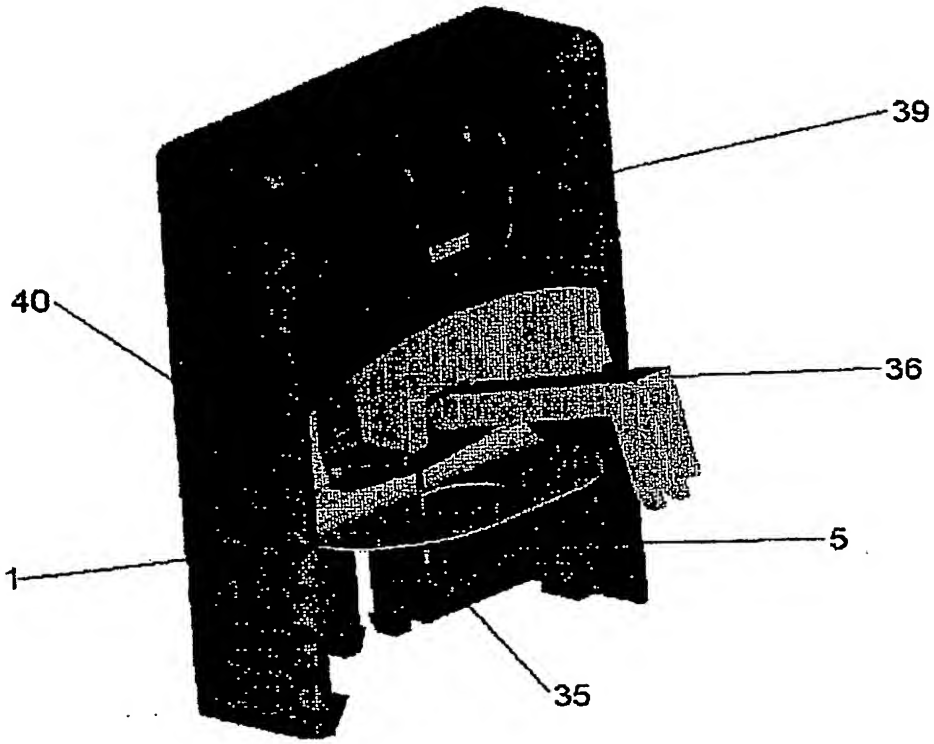


FIG. 14

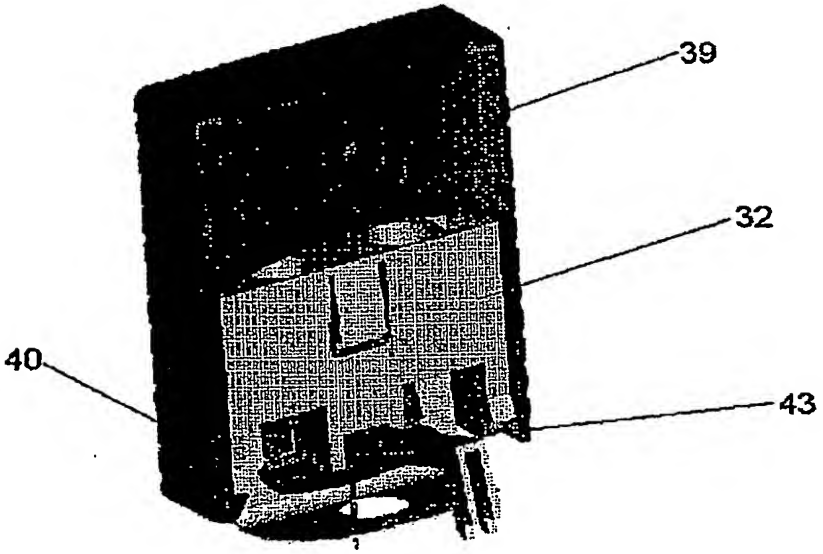


FIG. 15

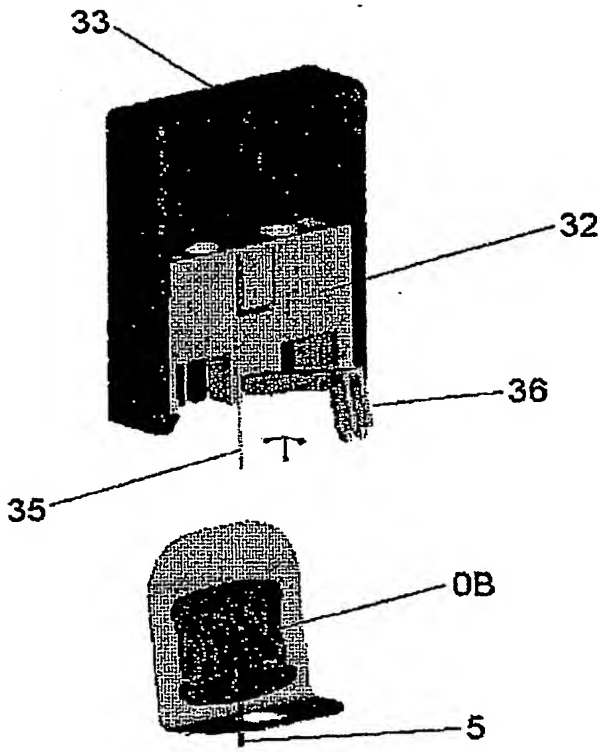


FIG. 16

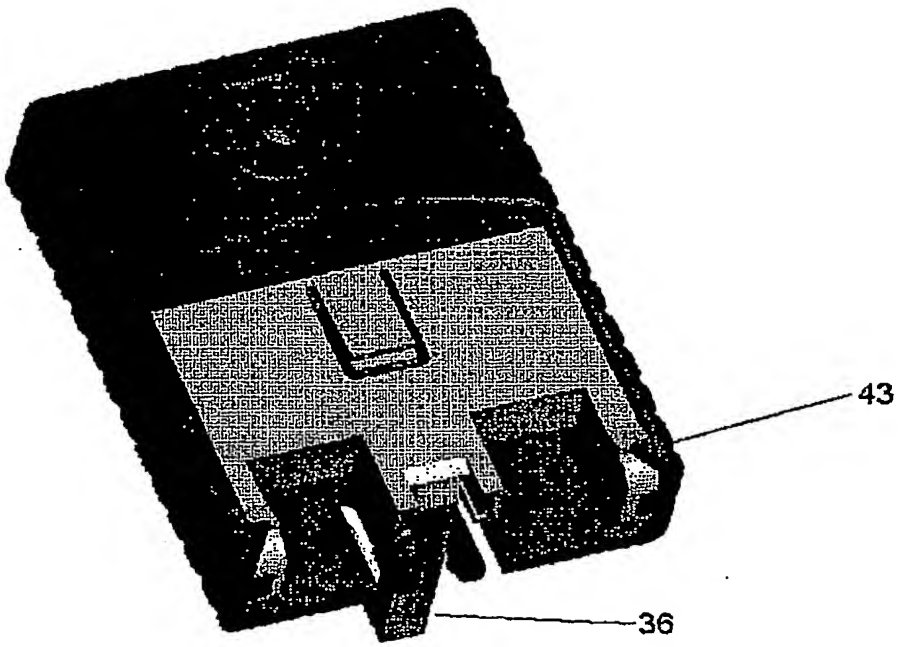


FIG. 17

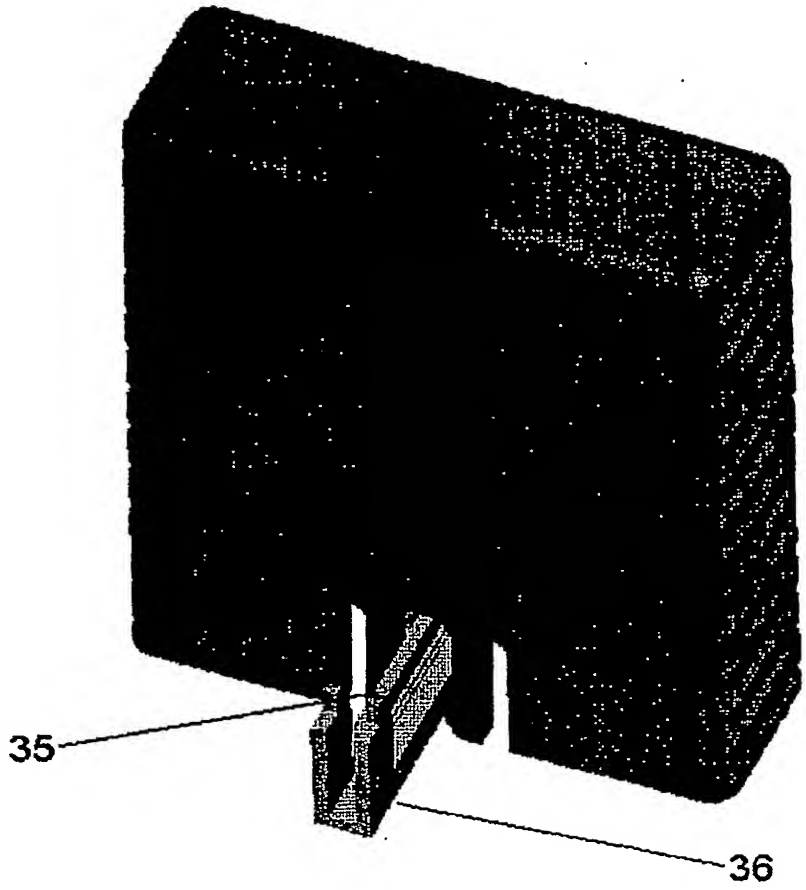


FIG. 18

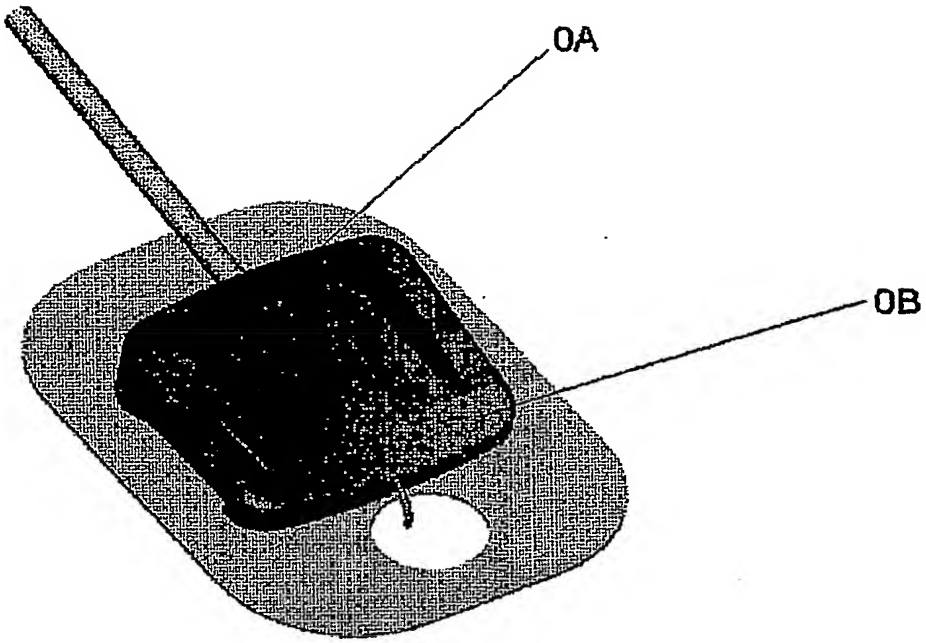


FIG. 19

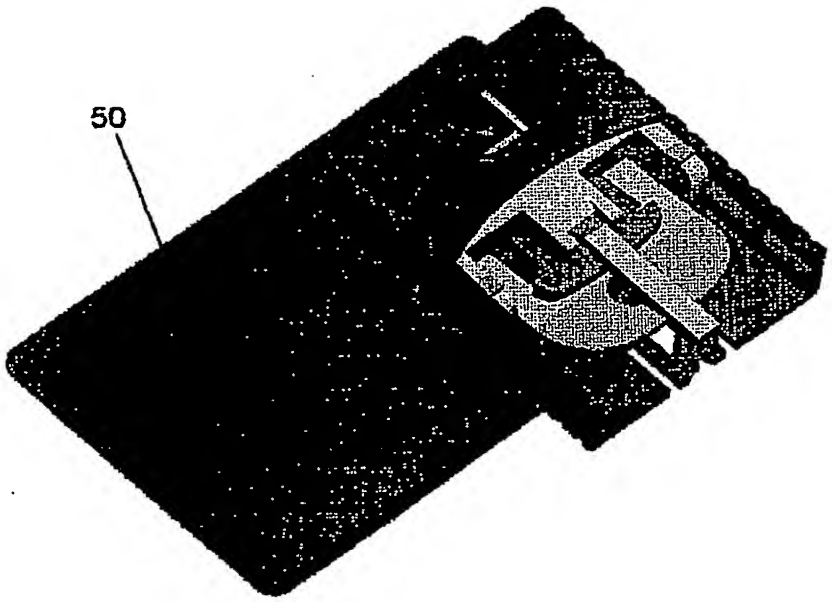


FIG. 20

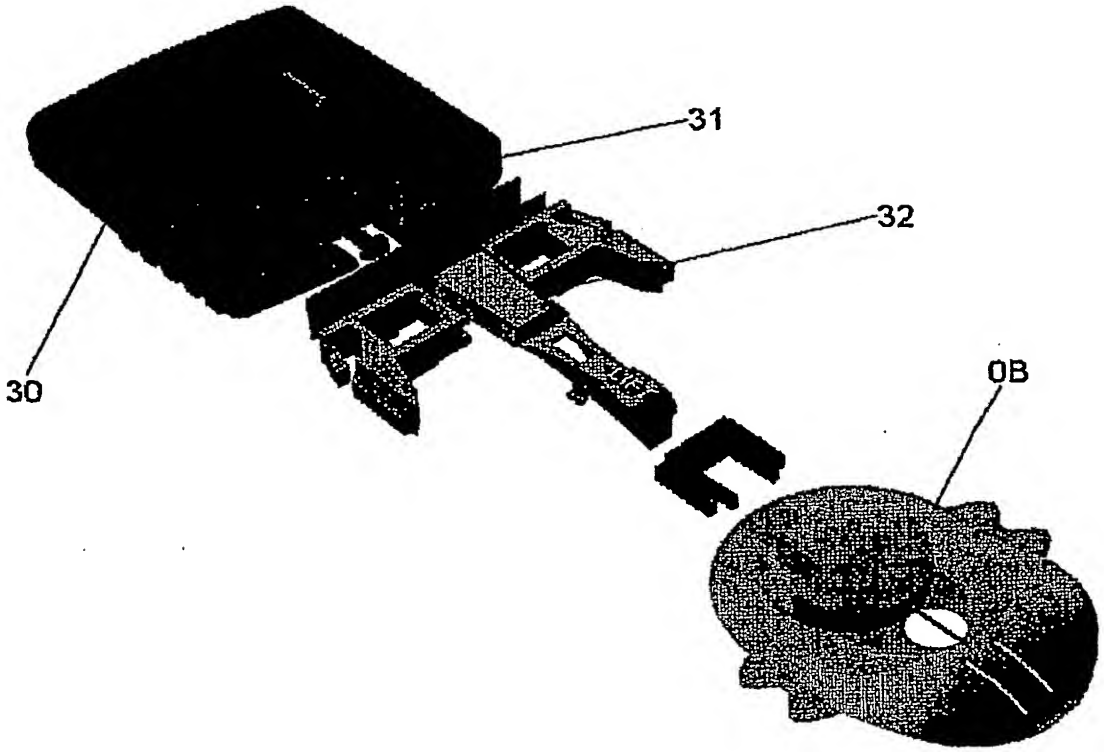


FIG. 21

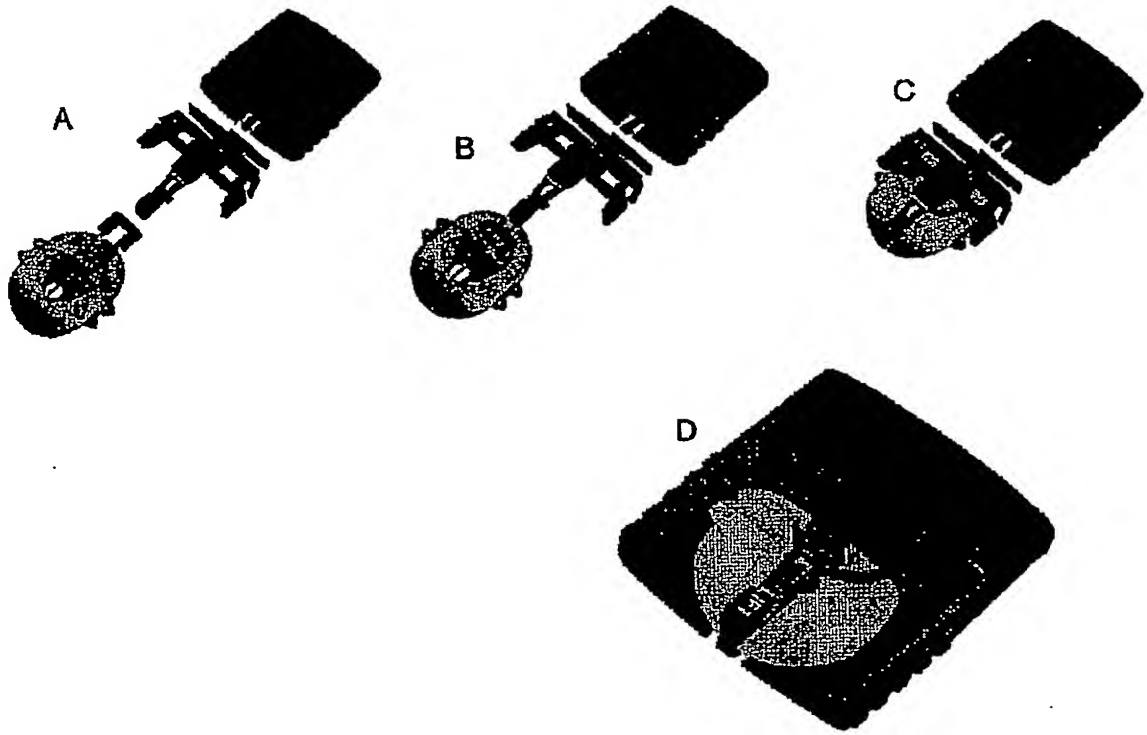


FIG. 22

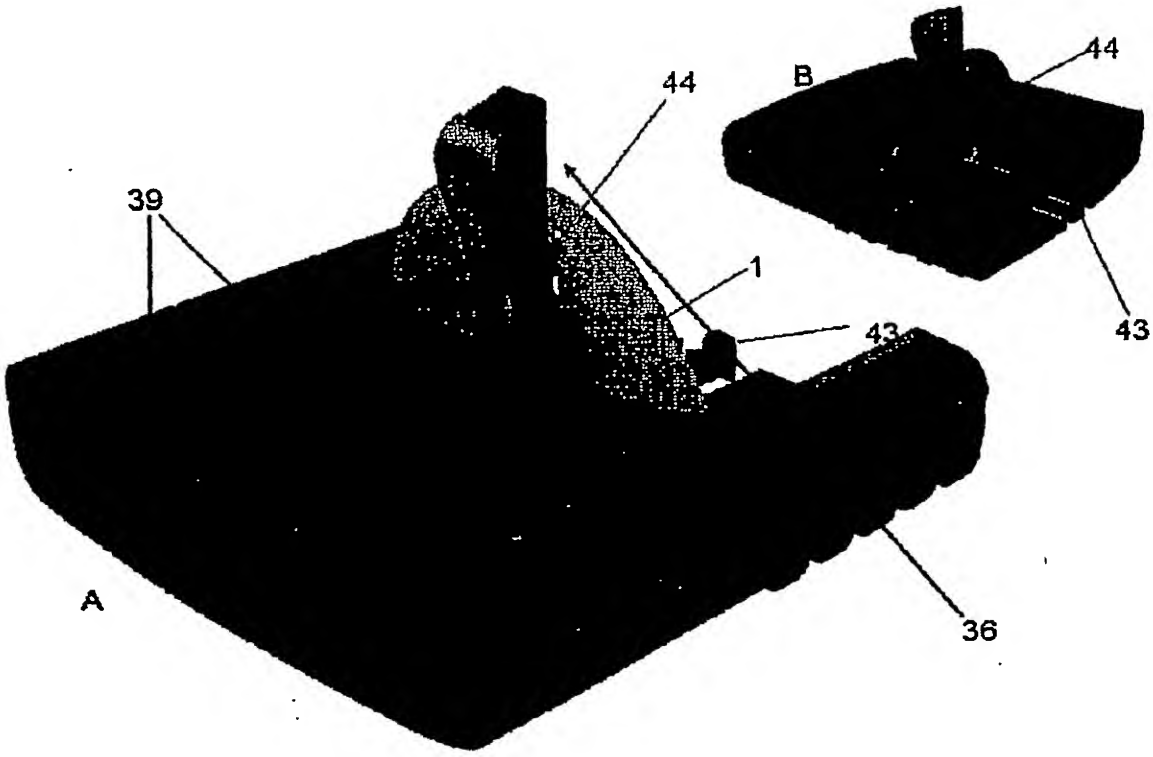


FIG. 23

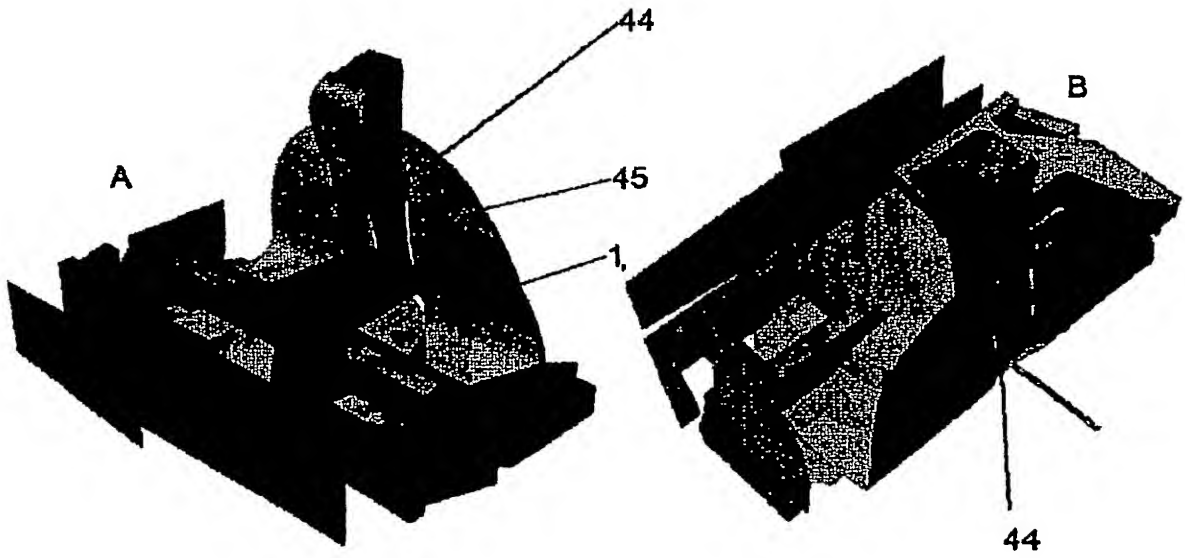


FIG. 24

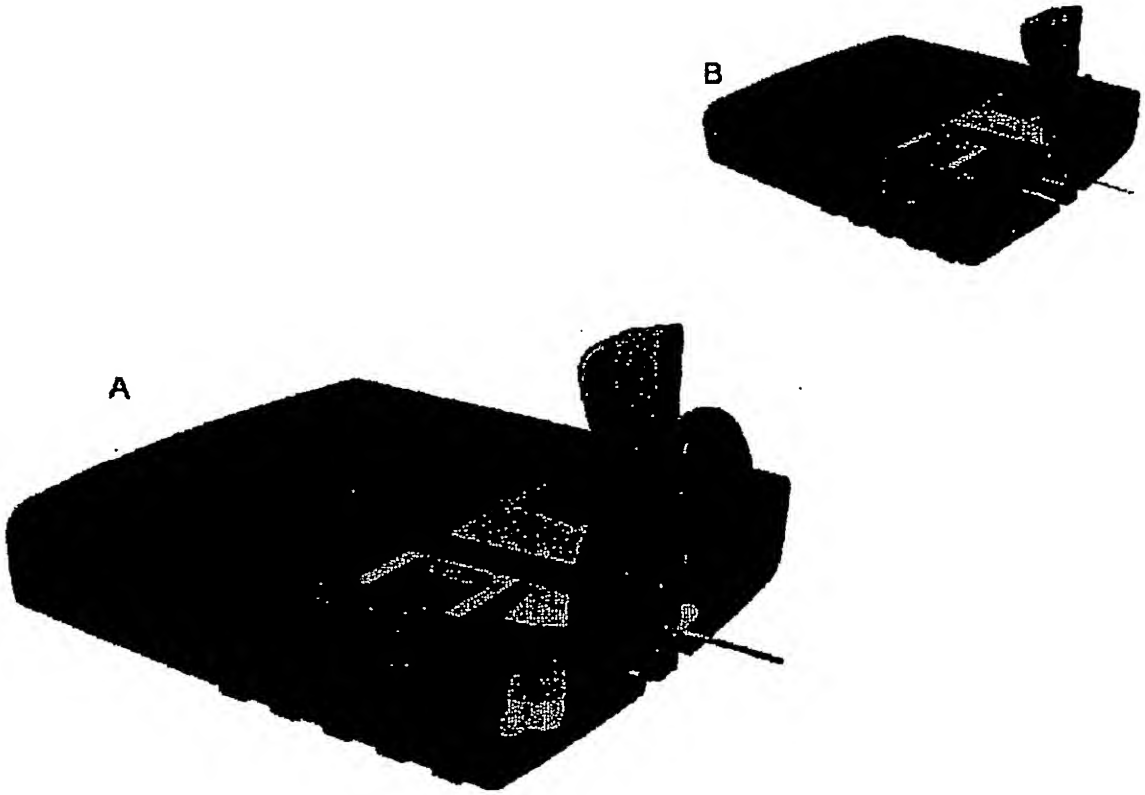


FIG. 25

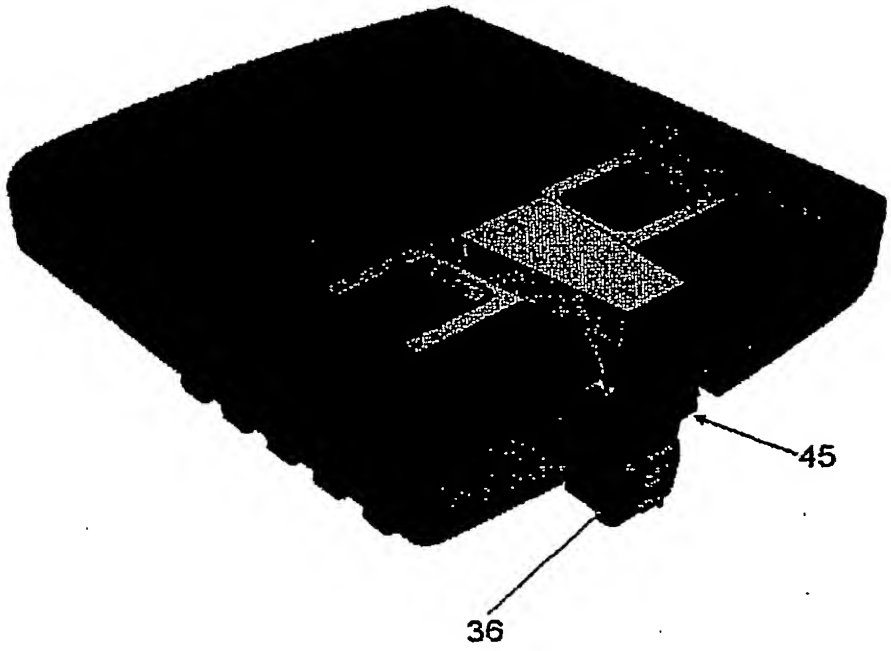
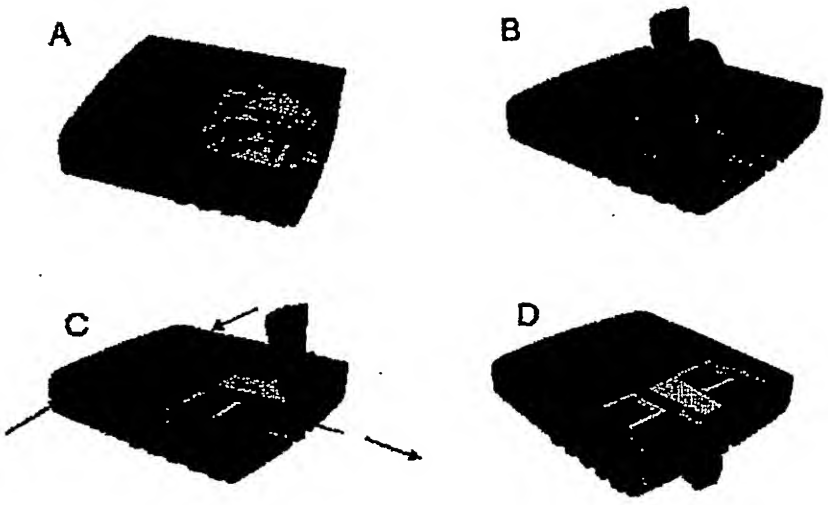


FIG. 26



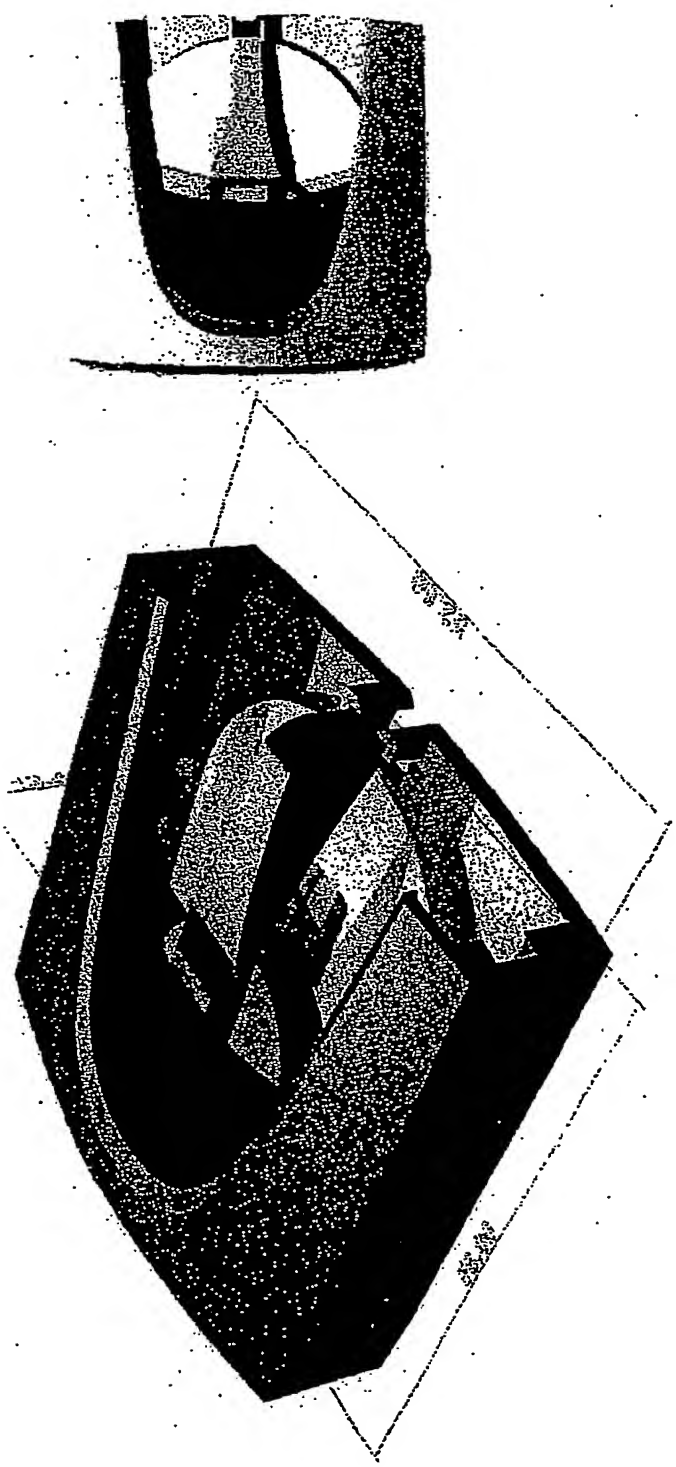
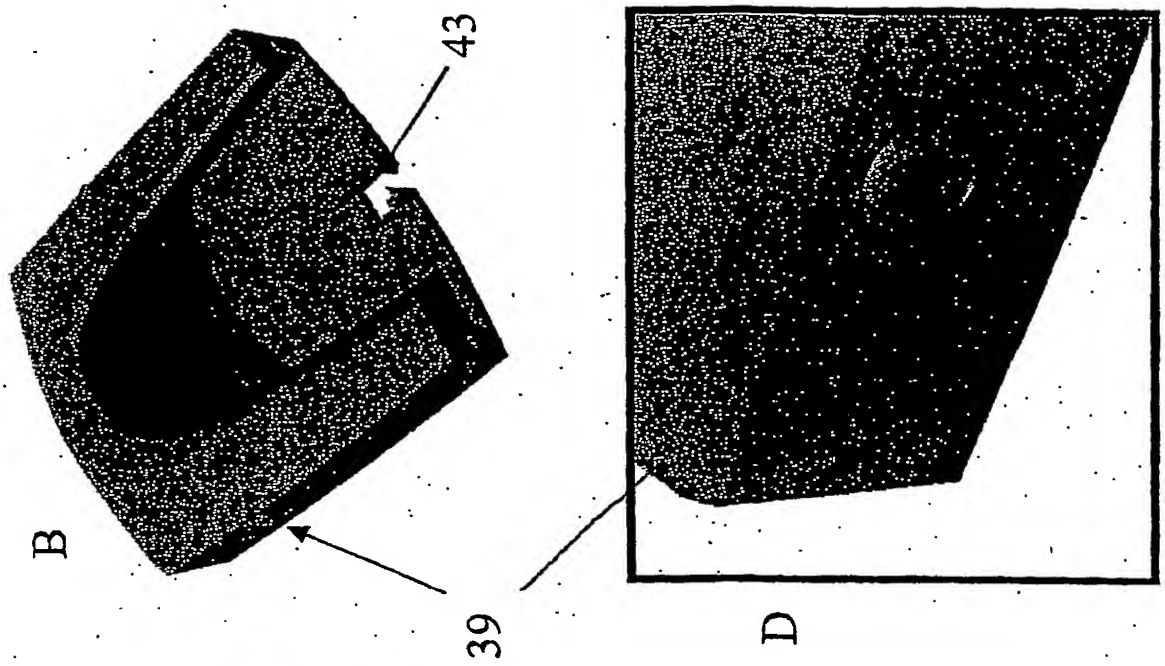


Fig. 27



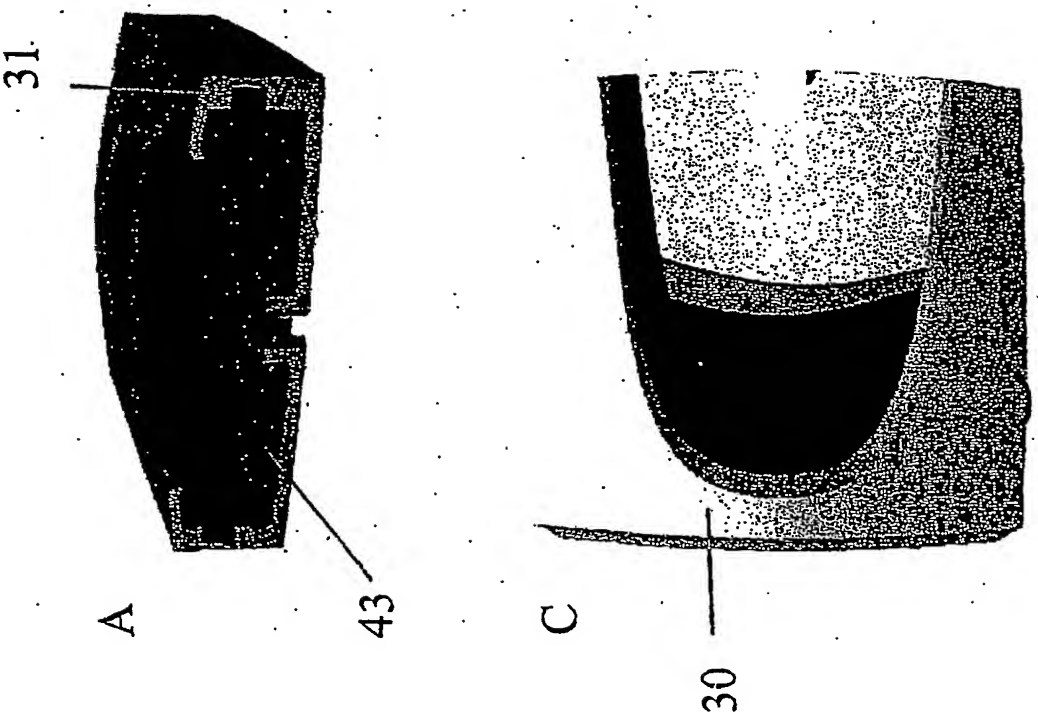
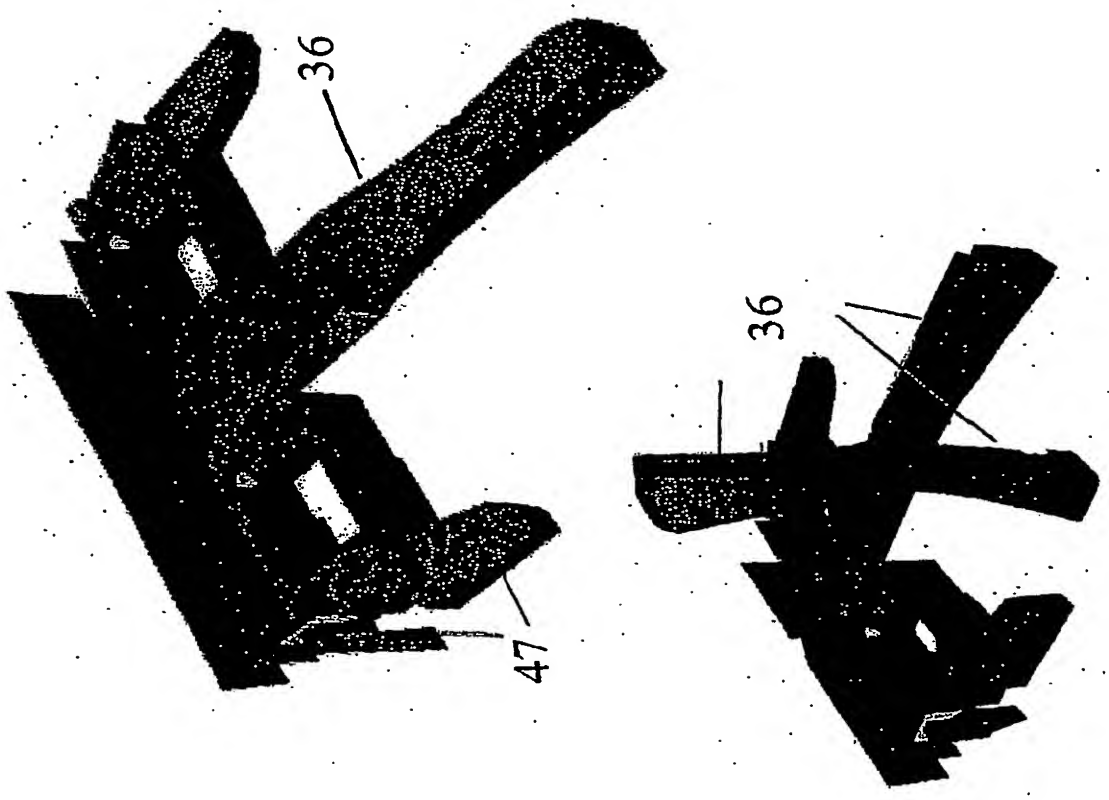


Fig. 28



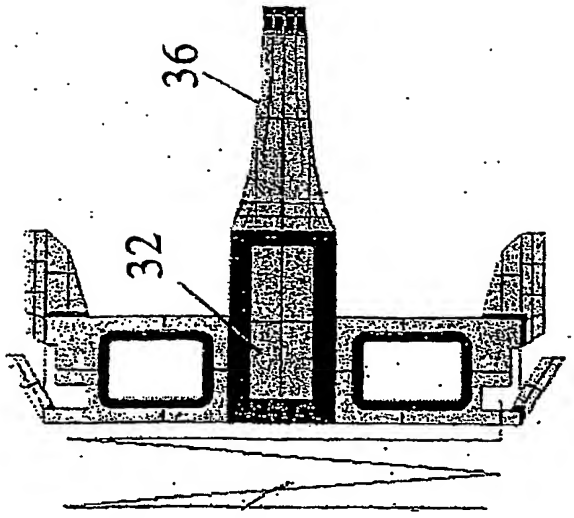


Fig. 29

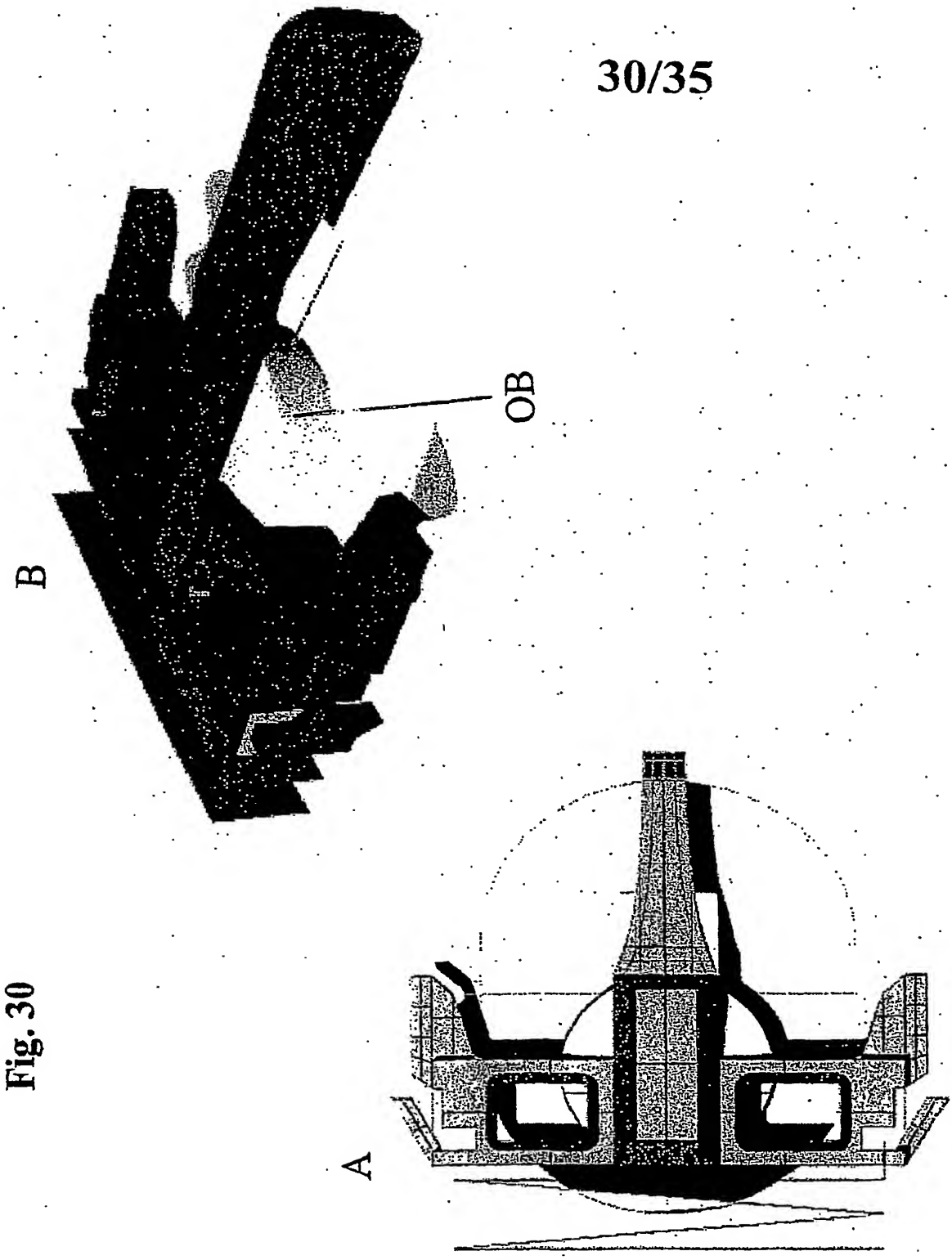


Fig. 30

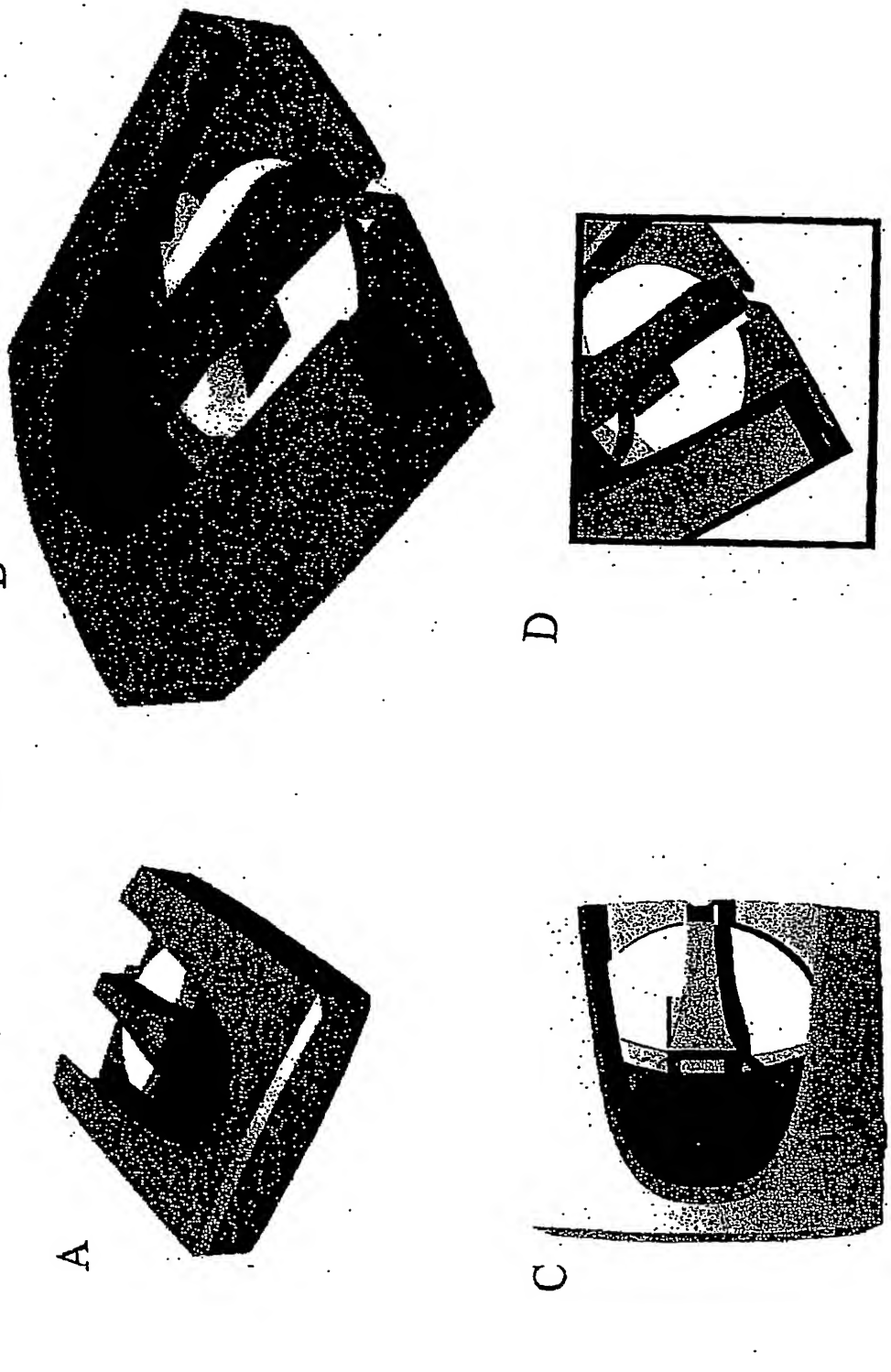


Fig. 31

Fig. 32

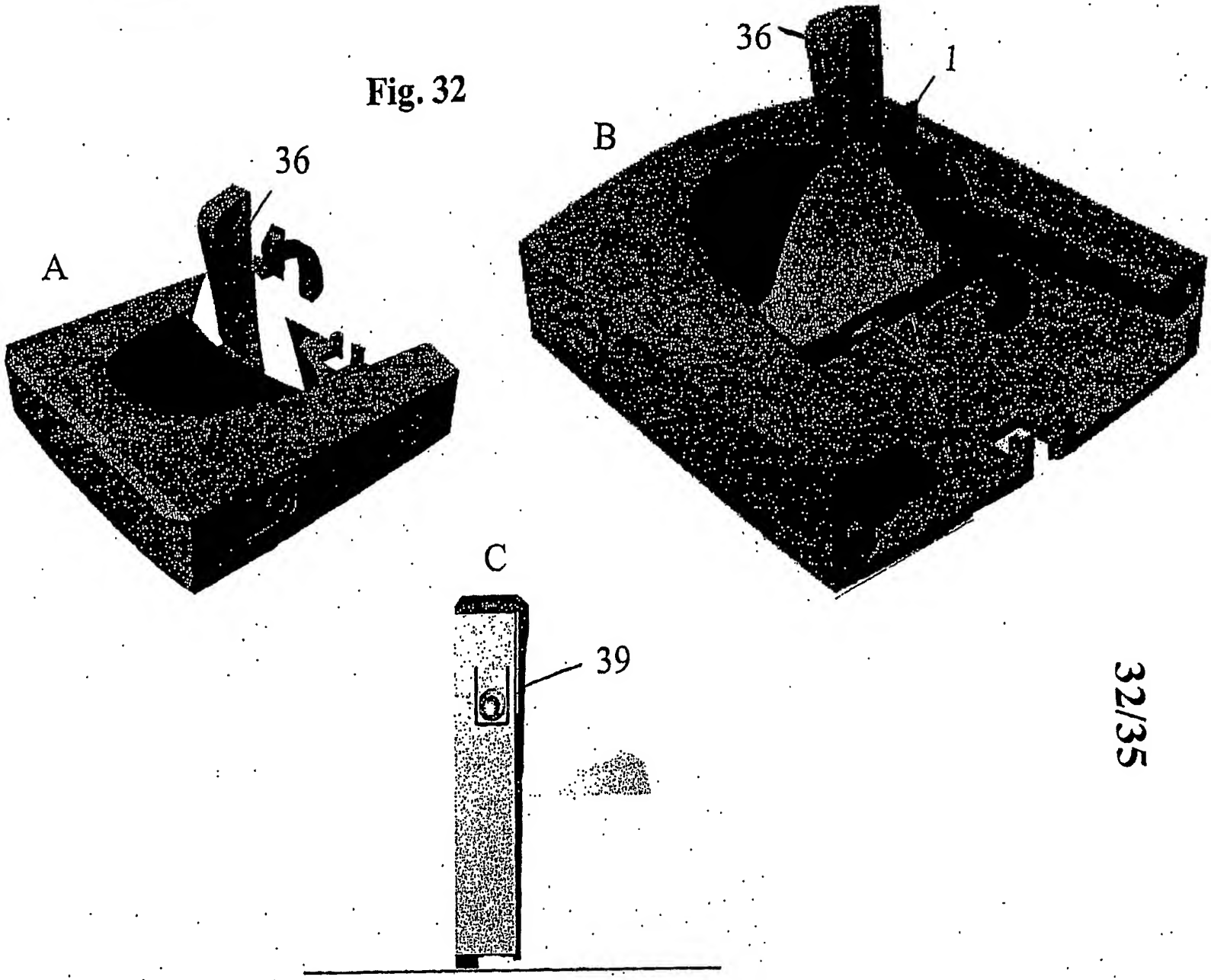


Fig. 33

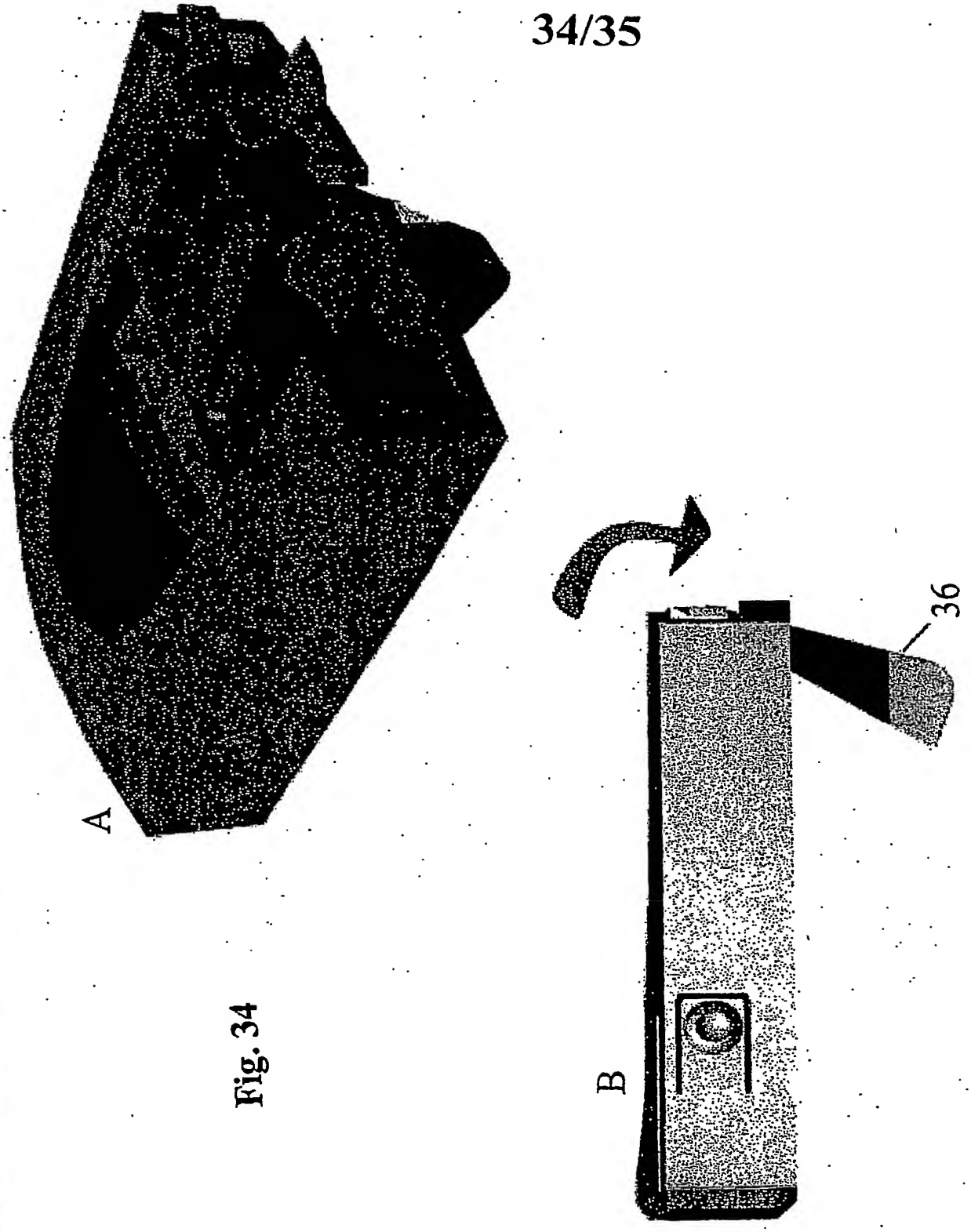


Fig. 34

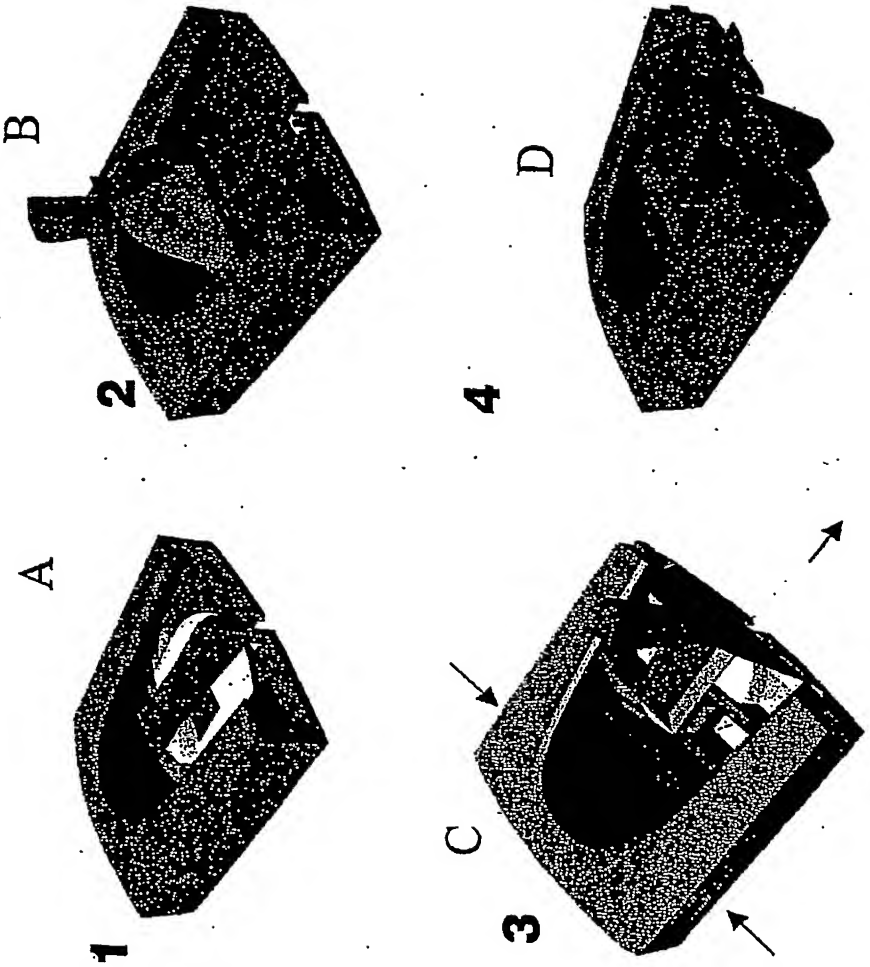


Fig. 35